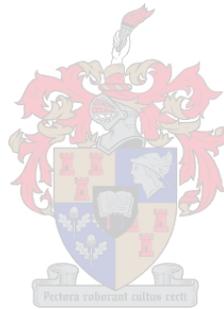




The Department of Community Health Sciences  
Stellenbosch University, South Africa

**DEVELOPMENT AND TESTING OF AN M-HEALTH PLATFORM TO  
REDUCE POSTOPERATIVE PENETRATIVE SEX IN RECIPIENTS OF  
VOLUNTARY MEDICAL MALE CIRCUMCISION**

Yoesrie Toefy



Stellenbosch 2017

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DEVELOPMENT AND TESTING OF AN M-HEALTH  
PLATFORM TO REDUCE POSTOPERATIVE  
PENETRATIVE SEX IN RECIPIENTS OF VOLUNTARY  
MEDICAL MALE CIRCUMCISION  
THESIS FOR DOCTORAL DEGREE (Ph.D.)

By

**Yoesrie Toefy**

*Principal Supervisor:*

Dr Donald Skinner  
Stellenbosch University, South Africa  
Department of Public Health Sciences

*Co-supervisor(s):*

Dr Sarah Thomsen  
Karolinska Institutet, Sweden  
Department of Public Health Sciences

Professor Vinod Diwan  
Karolinska Institutet, Sweden  
Department of Public Health Sciences

*Opponent:*

Dr Natalie Leon  
South African Medical Research Council  
Health Systems Research Unit

*Examination Board:*

Professor Anders Ahlbom  
Karolinska Institutet, Sweden  
Institute of Environmental Medicine

Professor Tamara Shefer  
University of the Western Cape, South Africa  
Department of Women and Gender Studies

Professor John Kinsman  
Umeå University, Sweden  
Department of Public Health and Clinical  
Medicine

Professor Leslie Swartz  
Stellenbosch University, South Africa  
Department of Psychology

Professor Maria-Theresa Bejerano  
Karolinska Institutet, Sweden  
Department of Microbiology, Tumor and Cell  
Biology



This thesis is dedicated to the men in the communities who generously gave of themselves to allow me this body of work.

The artwork on the cover is a word-cloud generated from the messages the men and their partners suggested to be included in the m-Health intervention



## ABSTRACT

**Background:** The widespread roll-out of voluntary medical male circumcision (VMMC) has been accompanied by reports of VMMC recipients, particularly men who are married or cohabiting, resuming sexual intercourse before the recommended healing period of six weeks. This behaviour carries an increased risk of transmission of STIs and HIV, for both partners. At the same time, it is unrealistic to assume that an already over-burdened health system will be able to provide repeated, intense messaging that recent recipients of VMMC may need to help them navigate the postoperative period sexually. There is an urgent need to develop culturally appropriate messages and innovative delivery strategies for behaviour modification in the postoperative period and in the longer term for medically circumcised men.

**Methods:** As a step to better understand the behaviour of the VMMC patients during the six-week recovery period, we conducted nine single-gender focus groups with males who had undergone VMMC in the previous six months and their partners (Study 1). Armed with this information, we strove to create a contextually-relevant message regime by using a staggered qualitative methodology: (1) focus group discussions with 52 recently circumcised men and their partners to develop initial voice messages (2) thematic analysis and expert consultation to select the final messages for pilot testing, and (3) cognitive interviews with 12 recent VMMC patients to judge message comprehension and rank the messages. The message content and phrasing were guided by the theory of planned behaviour, the health action process approach and the action research approach (Study 2). For the next two years, this intervention was evaluated using a two-armed, randomized, single-blind, controlled design. This sample was collected at 12 clinics in urban area of Cape Town in the Western Cape Province, South Africa. Patients were followed up at 42 days after enrolment (Study 3). As a final measure, the usability of the platform was evaluated. At follow-up, 597 participants completed questionnaires regarding the usability and user experience of the mobile audio platform. Usability was measured with the System Usability Scale (SUS). Five focus groups with a total of 25 patients were also conducted. The scale's multidimensionality was shown with the emergence of three trends that explained more than 65% of the total variance of the scale (Study 4).

**Results:** The primary motivation to VMMC uptake included religious injunction and hygiene reasons and protection against sexually transmitted infections not necessarily HIV. Both men and women felt that sex was important to maintain the relationship (Study 1). We received 245 messages with 42 themes. Expert review and cognitive interviews with more patients resulted in 42 messages with a clear division in terms of needs and expectations between the initial wound-healing recovery phase (weeks 1–3) and the adjustment phase (weeks 4–6). Participants were more positive and salutogenic than public health experts were (Study 2). The randomised controlled trial found a slightly larger positive effect in the Intervention Group (28.0%) than in the Control Group (32.3%) but not significant ( $p=0.071$ ) (Study 3). Participants gave the platform an overall usability score of 62.80 (SD 13.41). Most of them were positive about the messages (Study 4).

**Conclusions:** VMMC counselling needs to take into account the real-life context of the circumcised men. Due to systematic, social and cultural factors, there is a real risk that men in this population may initiate sex before complete healing has occurred (Study 1). Consultation with potential m-Health recipients and using classic behavioural theories are vital to the success of a programme (Study 2). Early resumption of sex after VMMC is common, warranting better counselling. M-Health technology is a potential tool but it should be complemented by other behaviour-change methods (Study 3). The results suggest that the audio messaging system has good usability, user experience and user acceptance (Study 4).

**Keywords:** m-Health; male circumcision; postoperative wound-healing period; health promotion; audio messaging; behaviour-change

## LIST OF SCIENTIFIC PAPERS

- I. Y.Toefy, D. Skinner, and S. C. Thomsen, “‘What do You Mean I’ve Got to Wait for Six Weeks?!’ Understanding the Sexual Behaviour of Men and Their Female Partners after Voluntary Medical Male Circumcision in the Western Cape. *PLoS One* 2015; 108 7): e0133156.
- II. Y. Toefy, D. Skinner, and S.C. Thomsen, “‘Please Don’t Send Us Spam!’ A Participative, Theory-Based Methodology for Developing an m-Health Intervention. *JMIR m-Health uHealth* 2016; 4(3): e100.
- III. Y. Toefy, D. Skinner, T.M. Esterhuizen, M. McCaul, M. Petzold, V. Diwan and S. Thomsen, Effectiveness of an audio-based cellular platform on increasing safe sexual behaviour during the healing period after male circumcision in Western Cape, South Africa (Unpublished, 2017).
- IV. Y. Toefy, D. Skinner, and S.C Thomsen, A mixed-methods evaluation of an audio-based m-Health platform designed to reduce penetrative sex in recently circumcised men (Submitted to *BMC Medical Informatics and Decision Making*: Manuscript Number: MIDM-D-17-00096, 2017).

## RELATED PAPERS

Thomsen Sarah C, Skinner D, **Toefy Y**, Esterhuizen T, McCaul M, Petzold M, Diwan V. Voice message-based m-Health intervention to reduce postoperative, penetrative sex in recipients of voluntary medical male circumcision in the Western Cape, South Africa: Protocol of a randomized controlled trial. *JMIR Research Protocols* 2016; 5(3):E155.

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## LIST OF ABBREVIATIONS

AIDS	Acquired Immune Deficiency Syndrome
DoH	Department of Health
GDP	Gross domestic product
HAPA	The Health Action Process Approach
HIV	Human Immunodeficiency Virus
ICT	Information and communication technology
LMIC	Low and middle-income countries
m-Health	Mobile health
PDA	Personal digital assistant
PEP	Post-exposure prophylaxis
RCT	Randomised controlled trial
SD	Standard deviation
SUS	System Usability Scale
TPD	The Theory of Planned Behaviour
VMMC	Voluntary medical male circumcision
WP	Western Cape Province

# 1 INTRODUCTION

## 1.1 GLOBAL HIV BURDEN

Since the beginning of the epidemic in the 1980s, the HIV virus has infected more than 70 million, while around 35 million people have since died of the disease. As of 2015, between 34.0 and 39.8 million people worldwide were living with HIV. Of these 1.8 million were children younger than 15 years old.[1] An estimated 0.8% [0.7-0.9%] of adults aged 15–49 years worldwide are living with HIV, although the burden of the epidemic continues to vary considerably between countries and regions. An estimated 2.1 million individuals became newly-infected worldwide with HIV in 2015, including 150,000 children under the age of 15 years.[2] Most of these children live in sub-Saharan Africa and were infected by their HIV-positive mothers during pregnancy, childbirth or breastfeeding. As of June 2016, 18.2 million people living with HIV had access to antiretroviral therapy (ART) globally, up from 15.8 million in June 2015, 7.5 million in 2010, and less than one million in 2000.[1] Currently, the number of people infected with HIV globally who know their status, is estimated to be 60%. The remaining 40% do not have access to HIV testing services.[3]

*Table 1: Newly infected HIV infections by region, 2015[1]*

Region	Total No. (%) Living with HIV	Newly Infected	Adult Prevalence [%]
<b>Global Total</b>	36.7 million (100%)	2.1 million	0.8
<b>Eastern and Southern Africa</b>	19.0 million (52%)	960,000	7.1
<b>Western and Central Africa</b>	6.5 million (18%)	410,000	2.2
<b>Asia and the Pacific</b>	5.1 million (14%)	300,000	0.2
<b>Western and Central Europe and North America</b>	2.4 million (7%)	91,000	0.3
<b>Latin America and the Caribbean</b>	2.0 million (5%)	100,000	0.5
<b>Eastern Europe and Central Asia</b>	1.5 million (4%)	190,000	0.9
<b>Middle East and North Africa</b>	230,000 (<1%)	21,000	0.1

Table 1 clearly shows that the majority of the HIV burden remains in Sub-Saharan Africa, especially in Eastern and Southern Africa followed by Eastern Europe and Central Asia.

## 1.2 SUB-SAHARAN AFRICA

The Eastern and Southern region of sub-Saharan Africa remains most severely affected, with 19 million [17.7 million–20.5 million] people living with HIV in that region. Women account for more than half the total number of people living with the disease. Although new infections declined by 14% between 2010 and 2015, there were an estimated 960 000 [830 000–1.1 million] new HIV infections in the region. This number accounts for 46% of the new HIV infections globally.[2] The same level of decline holds true for AIDS-related mortality

which fell by 38% to 470 000 [390 000–560 000] over the same five-year period in the Eastern and Southern African countries.

### 1.3 THE HIV EPIDEMIC IN SOUTH AFRICA

#### 1.3.1 Epidemiological context

Globally, South Africa has the largest HIV epidemic with an estimated seven million [6 700 000 - 7 400 000] people living with HIV in 2015. There were 380,000 new in 2015 while 180,000 South Africans died from AIDS-related illnesses in the same year.[4] Although South Africa's national HIV prevalence is 19.1% among adults (aged 15-49), the rate differs significantly between provinces. For example, the province of Kwazulu-Natal has an HIV prevalence rate of almost 40%, as compared to the lowest prevalence rate of 18% in Northern Cape and Western Cape.[5] There are several key populations at risk of HIV infection in South Africa for a variety of reasons. Among them are women, sex workers, children and orphans, men who have sex with men (MSM) and people who inject drugs (PWID).[3] Transmission of HIV in South Africa, however, remains almost exclusively through heterosexual sex.[3] The high prevalence rates mean that effective use of proven interventions is essential.

### 1.4 THE HEALTHCARE SYSTEMS IN SOUTH AFRICA

There are two parallel health systems in South Africa, a private healthcare system that is well equipped and staffed, catering for the wealthiest twenty percent of the population and a public health system that is chronically underfunded and short-staffed, that serves the vast majority of the South African population.[6] In 2005, South Africa spent 8.7% of its GDP on healthcare, which equated to US\$437 per capita. Almost 79% of doctors work in the private sector.[7]

The vacancy rate for doctors working in the public sector stood at 56% and for nurses 46% in 2013.[8] The Department of Health stated that only 3% of newly qualified doctors take up residency in rural areas despite the fact that half of South Africa's population lives in these areas.[9]

*Table 2: Public sector people-to-doctor and people-to-nurse ratio by province, 2015[9]*

Province	People-to-doctor ratio	People-to-nurse ratio
Eastern Cape	4 280 to 1	673 to 1
Free State	5 228 to 1	1 198 to 1
Gauteng	4 024 to 1	1 042 to 1
KwaZulu Natal	3 195 to 1	665 to 1

<b>Limpopo</b>	4 478 to 1	612 to 1
<b>Mpumalanga</b>	5 124 to 1	825 to 1
<b>North-West</b>	5 500 to 1	855 to 1
<b>Northern Cape</b>	2 738 to 1	869 to 1
<b>Western Cape</b>	3 967 to 1	1180 to 1
<b>South Africa</b>	<b>4 024 to 1</b>	<b>807 to 1</b>

Table 2 shows the high ratios of doctors to patients, especially in provinces that have a high rural sector such as the Free State, Mpumalanga and North-West. However, even in the Western Cape there are about 4,000 persons for every doctor and almost 1,200 for every nurse in the public sector.

The high vacancy rates of health care personnel in the public health system in South Africa have implications for the quality of care that can be provided.

#### **1.4.1 The South African response to the HIV/AIDS epidemic**

In response to the high HIV prevalence rates in South Africa, and following many years of AIDS denialism within the National Government that drove public health policy from 1999 to 2008,[10] a program to distribute anti-retroviral therapy treatment nation-wide was formed by the government. In late 2003, the Operational Plan for Comprehensive HIV and AIDS Care, Management and Treatment for South Africa was finally approved, which was soon accompanied by a National Strategic Plan for 2007–2011.[11] The next two iterations 2012-2016 and 2017-2022 have expanded on these goals.[5] The distribution of anti-retroviral therapy has been successfully distributed through the primary health care sector that is housed in the public sector.[11]

#### **1.5 HIV PREVENTION STRATEGIES IN SOUTH AFRICA**

The fight against the spread of HIV infection in South Africa is encapsulated in the South African National AIDS Council's (SANAC) five goals strategy. These goals are a combination of behavioural, biomedical, social and structural prevention approaches combined with sustained quality treatment and care, as well as wellness programmes. They are also geared to look at the social and structural drivers that drive our current epidemics across all sectors, how to influence the impact of these epidemics, and examine the management of the way we care for people affected by the disease.

### 1.5.1 Voluntary medical male circumcision (VMMC)

Voluntary medical male circumcision (VMMC) became an important strategy in the fight against HIV infection when research showed the reduced risk of male acquisition of HIV by as much as 60%. [10]–[13] WHO and UNAIDS issued a statement in 2007 that VMMC was to be recognised as an efficacious intervention for HIV prevention. They also recommended that VMMC should be promoted as an additional tool in the prevention of HIV in men. [14] A large proportion of sub-Saharan countries with high HIV prevalence were targeted for VMMC roll-out. [15] By the middle of 2014, over 5.8 million VMMCs had been carried out in the thirteen countries, over half of which occurred in 2013. [16]

There are some serious challenges that face male circumcision as a prevention strategy. The proclaimed protective factor of this medical procedure against HIV transmission [10]–[12] is mistakenly viewed by some as a fully protective measure and there are concerns that men who have been circumcised may be more inclined to partake in risky behaviours such as multiple sex partners and not using condoms. VMMC is also focussed on protecting men at the exclusion of women [17] and it focuses entirely on a biomedical method without looking at prevention strategies. [18]

In South Africa, a large proportion of the circumcision-seeking population is circumcised in terms of religious decrees and cultural tradition, and the procedure is most often carried out in traditional ceremonies without clinical staff, although this is changing somewhat. [19] For example, the Xhosa community, which constitutes the vast majority of the Black population in the Western Cape, incorporates male circumcision as part of the ritual transition into manhood. [22] The challenges associated with circumcisions performed in these groups are that the circumcision procedure often does not remove the foreskin completely and therefore is not often as protective and because of the non-surgical environment in which these operations take place, surgical infections are a common occurrence. [20][21]

The South African government had committed to rolling out VMMC as a vital strategy in its fight against HIV infection. [4] The goal was to reach over 4 million adult men by 2015. At the end of 2013, however, the VMMC programme had only performed approximately 1.3 million male circumcisions since it started in 2010, which was only 31% of the 4.3 million target by 2015/2016. [23] This remains a focus for activity and emphasis will be placed on growing the rate of circumcisions, including the use of civil society partners to carry out the procedure. [24]

Circumcision is provided as part of a comprehensive service at district hospitals and, HIV testing, counselling and HIV education are recommended before the procedure. [14] This requires higher levels of resources and will be difficult to maintain. [25] Some provinces have thus outsourced the service to non-governmental organizations (NGOs) who provide VMMC either in mobile camps or stationary clinics.

## **1.6 VMMC COUNSELLING ADHERENCE**

### **1.6.1 Early resumption of sexual intercourse after VMMC**

The World Health Organization (WHO) established clinical guidelines for the VMMC recovery period. Among the various wound management procedures, they recommend a six-week recovery period with no penetrative sex after the VMMC procedure to stop the transmission of STIs, including HIV.[12] A risk of early resumption of sex was identified and was associated with negative events such as penile wound tearing and infection.[13] This risk was amplified in an environment without proper counselling, education and follow-up.[14] This seems to be particularly an issue for married men. In a clinical trial with HIV-positive circumcised men in Rakai, Uganda in 2009, researchers found that despite intensive counselling, about 11% of study participants reported having engaged in one or more penetrative sexual encounters before certified wound healing.[15] Despite intensive pre- and post VMMC counselling within the trial, the group that was more at risk was the married group. This indicated a prevalent socio-cultural desire for quick restart of sex within a well-established relationship.[16] In a pragmatic observational study in Nyanza, Kenya, it was reported that 30.7% of the study subjects did not wait for the required six-week period to resume penetrative sex but it usually starts within 3-4 weeks after the circumcision procedure.[16] Likewise, it was also found that marriage and co-habiting was the strongest predictor of having early sex. The study reported 65.7% of married men resumed sex before the end of the wound-healing period. A recent study from Zambia also found that 24% of circumcised men resumed sex early, 46% of whom did so in the first three weeks.[17]

Health education messaging has to take cultural norms and the expectations surrounding sexuality into consideration when developing communication strategies. Qualitative research from Nyanza, Kenya, as well as other sites in the Sub-Saharan region indicates that the main complaint was that the postoperative abstinence period is spontaneously cited by uncircumcised men as a barrier to obtaining VMMC and that the six-week period was considered too long to abstain.[17] The younger men worried more about whether their female partners would seek sex elsewhere because they could not physically provide intimacy. The older men were also worried that it would not be possible to sleep in the same bed as their wives and abstain. Studies in Southern Africa around traditional circumcision also talk about the cultural phenomenon of “sharpened pencils” where the perception exist that circumcised penises heighten sexual pleasure, and therefore acts as an incentive for men eager to engage in sex as soon as they are able to.[18]

### **1.6.2 The programmatic gap in existing pre- and post-operative counselling and education**

The need for proper counselling and education during the wound-healing period stems around the need to adopt wound-safety behaviour. In the Rakai study, a higher infection rate among female HIV- partners of HIV+ VMMC recipients was reported.[15] This makes it imperative that all effort must be made to mitigate this risk during this period.[15] Mehta (2009), in a pooled analysis of three efficacy trials, acknowledged that the intensive counselling done

with the participants received is not reflective of the standard of care offered to VMMC recipients in these countries. The study found no additional risk for HIV acquisition for men who reported an early resumption of penetrative sex compared to men who did not.[19] Herman-Roloff, Bailey and Agot (2012) looked prospectively at the time it took to engage in sexual activity. They found participants who engaged in early sexual activity were more likely to be 25 years and older, working, and married, and HIV positive (Pearson's  $\chi^2 = 5.9$ ,  $p < 0.05$ ).[16] A second study conducted by Rogers et al (2013) also found that the risk factors of being married, older 25 years, being HIV-positive, consuming alcohol, and being multi-partnered are associated with early resumption of sex among men in Kisumu ( $n = 323$ ).[20] Clearly, this programmatic gap needs to be filled by using more innovative methods of postoperative counselling for recipients of VMMC. One possibility is m-Health.

## **1.7 M-HEALTH**

### **1.7.1 Mobile Health (m-Health) as a self-care strategy**

With more pressure on the public health sector in terms of budgets and staff shortages, programme developers have started to look at self-care programmes as a means to address some service delivery challenges.[21]. Despite the perceived benefits of such programmes, however, the idea of mobile phone technology to assist and deliver healthcare remains outside traditional healthcare channels. [22]

Figure 1[23] provides an overview of the current and potential uses of m-health. Disease management of diabetes, asthma, hypertension, obesity and HIV treatment are ideal candidates for m-Health programmes, in the form of mobile phone text messaging [24]–[28]. Mobile phone text messaging also assist in reducing alcohol consumption, stopping smoking, obesity management, and lastly, sexually transmitted infection, prevention and testing.[24], [26]–[28] Mobile devices are also used for data collection purposes, both in healthcare and biomedical research [23], [29], [30]. Medical education, clinical practice and support services are all good candidates for the use of m-Health.[31]–[33] Traditionally, the development of M-health interventions has always been concentrated in the high income countries, but as global mobile phone usage patterns have changed towards a concentration in low income countries, a string of mobile technologies have emerged from this region. [28], [34]–[36] Despite the recent upsurge of mobile use in low income countries, the physical infrastructure of the mobile and wireless networks have not been developed at a similar rate.[37][38] There is still a huge potential for M-health interventions to have positive effects on health outcomes.[35]

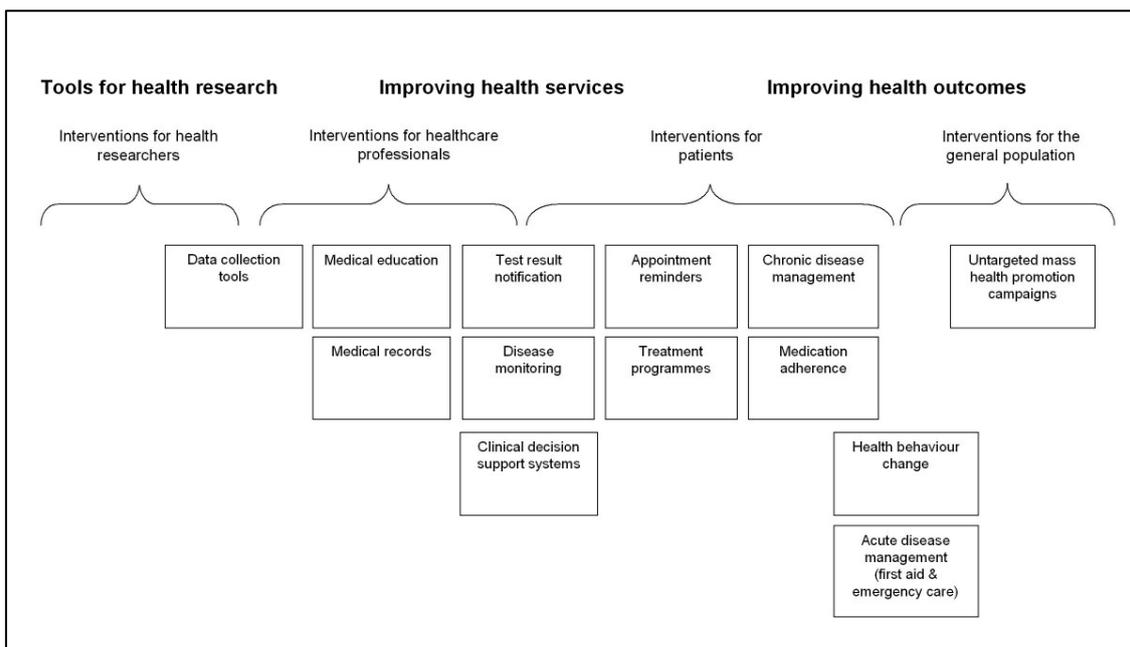


Figure 1: m-Health uses in the field (A. Chib, M. H. van Velthoven, and J. Car, 2014)

There is very broad ownership of cell phones in South Africa: 97% of household have a mobile phone, with the urban centres having a higher degree of saturation. Particularly within the urban setting there is little difference by income level in terms of access to phones.[32] With the near universal spread of cell phones in South Africa, mobile phone technology has been found to be viable for health services and feasible for HIV and AIDS-related prevention and services in South Africa,[33][34] and is now used in several health-related text-reminder projects in the country. [35][39].

The efficacy of m-Health interventions in the clinical environment is well-studied[22][40] but there is not much on the effectiveness of m-Health interventions on behaviour-change. Chib (2014) suggests that the existing feasibility studies on the first five columns of the m-Health categories in Figure 1, only focus on how feasible, implementable, adoptive and acceptable of the technology the user is, as opposed to their effectiveness on health outcomes.[23]

The majority of m-Health interventions with a messaging component have only used text messages (SMS). Text message reminders to improve medication adherence for people with chronic illnesses have been evaluated via randomised trials in Low to Medium Income Countries (LMIC)[38], [41]–[43]. Lester et al (2010) found in a Kenyan randomized controlled study that patients who received SMS support had significantly improved ART adherence and rates of viral suppression, compared with the control individuals (relative risk [RR] for non-adherence 0.81, 95% CI 0.69–0.94;  $p=0.006$ )[44][45]. In another Kenyan RCT, Pop-Eleches (2011) found similar success, where 53% of the participants receiving weekly SMS reminders achieved adherence of at least 90% during the 48 weeks of the study, compared with 40% of participants in the control group ( $P=0.03$ ).[45] Two recent systematic reviews found modest and suggestive evidence for the benefits of text-based m-Health technology[46].

### **1.7.2 Voice messaging m-Health interventions**

Voice message m-Health systems for behaviour-change are relatively under-studied, although there are a few published studies on its effectiveness. Voice messaging as an intervention has been used effectively in the fields of nutrition and weight-loss and smoking cessation programmes. In Nigeria, a behaviour intervention using a combination of approaches, including voice messaging, were used to change or enforce breastfeeding patterns.[47] A study trying to improve the adherence to diabetes treatment used voice messages successfully.[48] On the other hand, De Costa and her team (2010) found that voice message reminders had no effect on adherence in antiretroviral treatment in South India.[49][50].

A Cochrane review from 2013 found only one RCT of a telephone-delivered intervention to increase uptake of post-exposure prophylaxis (PEP) for rape victims, for preventing HIV infection in HIV-negative persons. A counsellor followed participants up telephonically throughout the 28 days when they had to take PEP treatment. The aims of the intervention were to encourage the participants to stay on treatment, to seek support from significant others, to attend counselling, to read and understand the information pamphlet, to utilise the medication diary and to return to the clinic for the follow-up. The estimated effect of telephone counselling was 6.5% (95% CI: 4.6 to 17.6%) and not statistically significant (P=0.13).[51]

### **1.7.3 The need for theoretical frameworks in the development of m-Health interventions**

Health behaviours are strongly affected by experiences, perceptions, and mental capacities of individuals, which are informed by social environments.[52] There are theories of behaviour-change that are well validated and well tested on evidence-based interventions. Research shows us that these grounded interventions are few and far apart.[53] Tomlinson et al (2013) contends that down-stream interventions, which are programmes that were only designed based on information transfer only, will fail at their implementation phase.[54]

Effectiveness studies of m-Health interventions that do not consider the nature of behaviour-change may find false negative results. That is, if the intervention shows a negative result, and the designers are only focused on the technology, they may decide that the intervention is not effective because of design reasons - such as usability of the platform - and thus may reject it. However, the intervention may have been ineffective because it did not take into account how individuals make decisions about their health. Therefore, a plausible theory of behaviour-change with the m-Health interventions should be guided by more than one technique depending on the targeted behaviour. The dynamic nature of the changing technology arena demands that m-Health researchers must be more innovative in their methodology and use appropriate methods throughout the development cycle. Novel research methods allow researchers to capitalise on technological advances and disseminate research findings more rapidly.

The theory of Planned Behaviour and the Health Action Process Approach (HAPA) are two behaviour-change theories that are often used in the public health arena.[55]–[59] The former being a cognitive theory that, in general, predicts that a set of beliefs will predict a desired behaviour outcome, while the HAPA is a stage-step theory that ‘moves’ the individual one step following the other towards the achievement of the desired behaviour.[58][60]

### ***The Theory of Planned Behaviour***

The Theory of Planned Behaviour (TPB) is a theory that provides the impetus of many behaviour-change interventions that exist today.[61] In 1991, Icek Ajzen proposed it as a process to improve the predictive power of the Theory of Reasoned Action. This was done by including perceived behavioural control to the existing TPB’s model. The Theory of Reasoned Action was formulated eleven years earlier by Ajzen and Fishbein [62] and this behavioural theory suggests that human behaviour is guided by three kinds of beliefs and norms: behavioural, normative and control. In combination, "attitude toward the behaviour," "subjective norm," and "perceived behavioural control" lead to the formation of a "behavioural intention". In the realm of messaging development, the first norm, behavioural attitude, convinces the participants of the usefulness, worth, and advantages of the proposed behaviour. Thus, the Theory of Planned Behaviour proposes that when individuals are convinced of the worth of the behaviour are more likely to adopt it. This theory is interesting for the development of the *content* of behaviour-change messages.[63]

In an Australian study on improving hand hygiene among health care workers, White et.al (2015) used a planned behaviour framework to explore in a systematic way, the underlying beliefs of nurses’ hand hygiene decisions according to the five critical moments as set out by the WHO hygiene framework. The study found a combination of the three elements of planned behaviour, namely, behavioural, normative and control beliefs influenced the level of commitment of the nurses to improve their own hand hygiene practices. The framework focused on the three elements of the model. It looked at *individual strategies* to counter the distraction from other duties the nurse must fulfil; it looked at *peer-based initiatives* within the workplace that were designed to foster a sense of shared responsibility on the issue of hygiene, and finally, it proposed *management-driven solutions* to tackle staffing and resource issues. This theory is thus appropriate for use in designing messages for concrete behaviour change.[64]

### ***The Health Action Process Approach (HAPA)***

The Health Action Process Approach (HAPA) is an open behavioural framework that consists of a variety of motivational and volitional constructs.[65] These constructs are proposed to describe and calculate individual changes in health behaviours in domains such as smoking or drinking cessation, dental hygiene, condom use, breast self-examination, dietary behaviours[66] and avoiding drunk driving.[67] This approach is based on the assumption that the adoption, initiation, and maintenance of these behaviours should be conceived of as a structured process including a motivation phase and a volition phase. The

former describes the intention formation while the latter refers to planning, and action (initiative, maintenance, recovery). Self-efficacy at the different stages of health behaviour-change is also central to the HAPA model.[68] We could not find the HAPA model used in any HIV prevention messaging intervention in the literature.

### ***The Action Research Approach***

In addition to the two behaviour-change theories, the study also used the Action Research approach. This approach was developed by Jacobs and Graham (2016), who linked iterative health behaviour intervention development and research methodologies and concluded that the requirements and solutions of these methodologies were evolved through collaboration between the developers and their intended target audiences. The method promotes adaptive planning, evolutionary development and delivery. It also encourages rapid and flexible response to change and allows a project to adapt to changes quickly.[69] Several m-Health intervention development programmes have previously concluded that partnering with the target population in the message development is critical to ensure that both a salient final product and feasible protocol are created.[70]–[72]

The Action Research approach was applied in two levels in our message development. First, recent recipients of VMMC and female partners of VMMC recipients were asked to come up with messages that they thought would be helpful during the recovery period through focus group discussions. Then, the participants in cognitive interviews verified these messages through explanation and ranking.

The other level in which Action Research approach was used was in the progression and rate of the messages. The ordering of the messages was designed to assist with the resolution of a particular issue or crisis as they occurred during the six-week period as highlighted by the participants. The progression of issues in the six-week period also dictated the rate the messages were delivered to the participants.

## **1.8 PROBLEM STATEMENT**

Several studies have shown that men recovering from VMMC, before the penile wound is healed, engage in penetrative sex during their recovery period. This leads to an increased risk of transmission of STIs, including HIV, in the immediate postoperative period after receiving VMMC. Recommendations have been made for developing and evaluating optimal counselling strategies among men seeking VMMC and to assess the effectiveness of behaviour-change communication strategies [21]. There is also recognition that a lack of human resources presents a barrier to the provision of such intensive services, particularly if repeated messaging is to occur. M-Health has been proposed as a method of reducing burdens on the health system in resource-poor settings. However, there is a lack of theory-based m-Health intervention development. Additionally, there is very little evidence in general of the effectiveness of m-Health interventions for behaviour-change.

## **1.9 AIM**

The overall aim of the study was to develop and evaluate – through a randomized, controlled trial – a voice message system to increase the adoption of safe sexual behaviour during the postoperative period for medically circumcised men in the Western Cape Province, South Africa.

### **1.9.1 Specific aims of the studies**

- To develop an understanding of the study population's sexual behaviour and perceptions during the six-week postoperative period following VMMC in the Western Cape Province. (Study I)
- To develop comprehensible and acceptable messages about safe sexual behaviour during the healing period for recipients of male circumcision in the Western Cape Province using a theory-based, participatory approach. (Study II)
- To assess the effectiveness of a voice message system on increasing safe sexual behaviour during the healing period for recipients of male circumcision in the Western Cape Province. (Study III)
- To assess the usability of an audio-based cellular platform to improve counselling about safe sexual behaviour during the healing period for recipients of male circumcision in the Western Cape Province. (Study IV)



## 2 METHODS

### 2.1 STUDY SETTING

#### 2.1.1 The Western Cape and the City of Cape Town municipality demographic and socio-economic indicators

The research for this thesis was conducted in the City of Cape Town municipality of the Western Cape Province of South Africa. Below follows a brief introduction of the demographic and socio-economic background of the province and its sub-structures.



Figure 2: The Provinces of South Africa

The Western Cape Province is one of the nine provinces of South Africa. It is situated in the south-western part of the country. It is the fourth largest province in South Africa, at 129,449 square kilometres. (Figure 2) It also has the fourth largest population of South Africa (11.3%), with 6.2 million inhabitants living in 1,634,000 households.[73] The population density of the Western Cape is 45 inhabitants per square kilometre and the household density is 12.6 persons per square kilometre.



Figure 3: The municipalities of the Western Cape

The Western Cape's total gross domestic product (GDP) for 2016 was R424bn (US\$29.3bn), making the province the joint second largest contributor to the country's total GDP (14%). It also has one of the fastest growing economies in the country, 2.7% in 2016.[74] The average annual household income of the Western Cape is R57,300 (US\$4,275), the second-highest in the country after Gauteng and almost double the national average of R29,400 (\$2,192).[75] According to Figure 4 about 20% of the population of the province live on under R10,000 (US\$740.88) per year, which is well under the established poverty line in South Africa.



Figure 4: Annual household income Western Cape

The Western Cape and Gauteng are the only two provinces in South Africa to have a positive migration trend. In other words, more people migrate into these two provinces than migrate outwards.[76] There is a high level of economic migration into the Western Cape, as roughly 16% (894,289 people) of the Western Cape's population in 2011 were born in the Eastern Cape, 3% (167,524) in Gauteng and 1% (61,945) in KwaZulu-Natal. People born outside of South Africa amounted to 4% of the province's population or 260,952 people.[74] As of September 2012, 69% of the population aged 15–64 are economically active, and of these 25% are unemployed.[75] This is slightly lower than the national unemployment rate of 26.5%.[75] The economic sectors that hold most of our labour force are finance, insurance,

property and business services; manufacturing and wholesale and retail trade, catering and accommodation.

At 45.4%, the largest racial group in the City of Cape Town Municipality is Coloured<sup>1</sup>, followed by White (42.7%). The African grouping (8.6%) and Indian/Asian groups (1.4%) are in the minority (Table 3). We find the same racial pattern in the greater Western Cape with the exception of the White and the African groupings swapping rankings in the broader province.[77] This is evidence of a high concentration of African communities in the rural and smaller town in the Western Cape.

Table 3: Racial breakdown in the City of Cape Town and the Western Cape overall

Percentage share by race group	City of Cape Town	Western Cape
Coloured	45.4%	42.4%
White	42.7%	15.7%
African	8.6%	38.6%
Indian/Asian	1.4%	1.4%
Other	1.9%	1.9%

The studies were conducted in the catchment areas of twelve public health clinics (Appendix 1) with MMC clinics in City of Cape Town municipality (Figure 5). Studies 1 and 2 used the same population drawn from the Heideveld Public Health Clinic and Mitchell's Plain Hospital in the Central Sub-structure. Study 3 selected its population from all twelve VMMC clinics in the Southern, Northern and Central Sub-structures, while Study 4 selected its participants from the intervention arm of the RCT in Study 3.

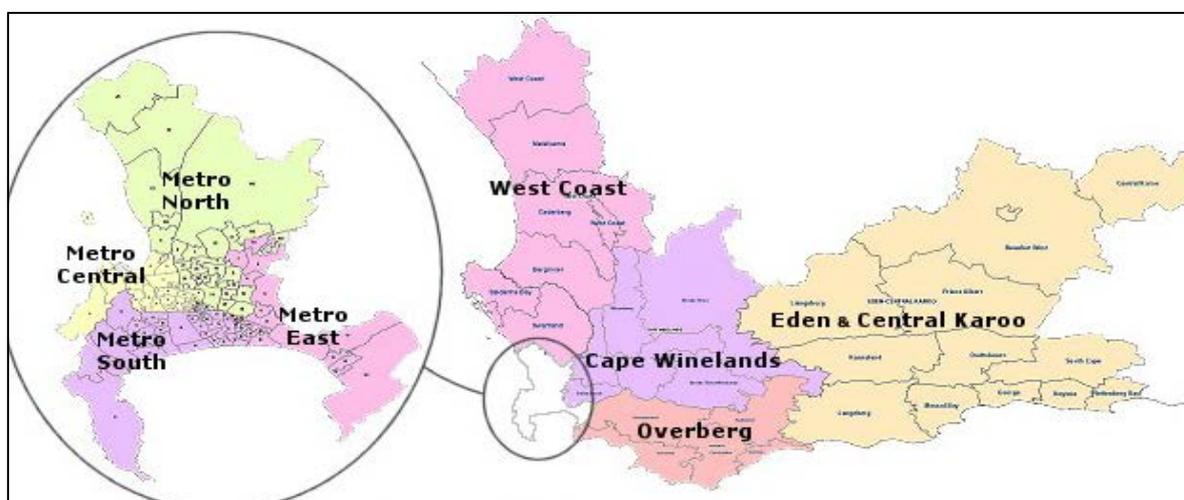


Figure 5: Western Cape municipal health regions and the City of Cape Town health sub-structures

<sup>1</sup> The term Coloured refers to an official South African race group that is predominantly mixed ancestry that is used in research and census data. These racialized terms were used in apartheid and they are still being used for affirmative purposes and since they speak to identities that in spite of being created and regulated by colonial and apartheid histories continue to have salience in modern South African society.

The province is divided into six municipal districts (Figure 5) with about two-thirds of inhabitants living in the municipal district of the City of Cape Town, also known as the Cape Metro. The Cape Town municipality's urban geography is influenced by the contours of Table Mountain, its surrounding peaks, the coastline, the Durbanville Hills to the north, and the expansive lowland region known as the Cape Flats.

The suburbs on the coastline and on the slopes of Table Mountain and surrounding mountains contain a large number of wealthy communities with an income of R2.5-million a year or more.[76] These communities are almost exclusively White. The Cape Flats, on the other hand, are a combination of low-cost housing and slum areas.[77] There are also wide belts of semi-rural farming areas on the Flats. According to the 2013 tax statistics, the average taxable income of the City of Cape Town municipality is R241,704.[76]

The majority of the townships<sup>2</sup> in the Cape Town area are densely populated (population density 9,600 per km<sup>2</sup>[73]) with a low socio-economic base and an unemployment rate of 20.9%.[75] The housing is typically one to two-bedroom maisonette-styled housing with an average population density of 9,600 per km<sup>2</sup> and an average house density of 4.57. The community is predominantly Christian but there is a large Muslim population (10–15%) in the townships.[78]

Between 2001 and 2010 the City's Gini coefficient, a measure of economic inequality, improved by dropping from 0.59 in 2007 to 0.57 in 2010 only to increase to 0.67 by 2011/12. A Gini coefficient of 0.67 points to a very unequal society as the international alert line for high inequality is only 0.4.

### **2.1.2 HIV and risk factors in City of Cape Town municipality**

The South African HIV prevalence rate varies widely according to race: from 31.7% among the Black group to 2.2% among the White group, with the Coloured's prevalence rate at 7.5% according to national antenatal data.[5] The Coloured community has a rising adult HIV prevalence trend as it was 7.0% in 2010, 7.6% in 2011 and 7.5% in 2012.[8]<sup>3</sup> The heightened HIV risk in this population group is fuelled both by a normal combination of socio-cultural, behavioural and epidemiological contributory factors,[79] and the reported incidence of high illicit drug and alcohol use prevalence in some sub-sectors of the community, which is statistically associated with risky sexual behaviour.[8], [9] It has a high level of gangsterism in the townships that serves to weaken the fabric and rules of the community.[80] The Coloured community has historically had a lower level of HIV infection, and do not see themselves as vulnerable. There is a strong undercurrent of racism and stigma in the community as HIV is seen as a 'Black' disease or a disease that belongs to other distant

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<sup>2</sup> (Term used in South Africa) A suburb or city of predominantly non-White occupancy, formerly officially designated for black occupation by apartheid legislation.

<sup>3</sup> There are no updated HIV prevalence data broken down by racial groups beyond 2013.

communities.[81][82] This has implications for the kind of HIV prevention messaging that is effective in this community.

### ***Healthcare in the City of Cape Town***

In the municipal region of the City of Cape Town, there are 164 healthcare facilities operational in the city, some operated by the Department of Health (DOH), while others are operated by the City of Cape Town. Primary health care services are provided by 153 fixed and mobile clinics throughout the region. Public secondary care services are provided by nine district hospitals and two regional hospitals.[83]

### ***HIV prevention and VMMC service delivery in the City of Cape Town municipality***

In 2014, the Provincial Department of Health released the Provincial Strategic Plan on HIV, STI and TB, in which it spelled out its broad 20-year plan through four objectives:[84]

- Concentrate on the social and structural approaches to HIV and TB prevention, care and impact
- Utilise all resources to prevent new HIV and TB infections
- Sustain health and wellness
- Protect human rights and the promotion of access to justice

VMMC is a critical area of the Department of Health's national strategic plan and is available at all the major clinics in each sub-structure. There are one mobile VMMC team per sub-structure, and the patients are recruited by themselves, the medical staff at the clinic or an DoH appointed non-profit organisation who access the community structures and networks to recruit VMMC patients. The other areas include the promotion of HIV testing through the HIV counselling and testing campaigns, the promotion of both male and female condoms, facilitate behaviour-change to reduce transmission risk factors, promote active TB case finding and promoting adherence to treatment until completion and finally, to promote social mobilisation to encourage the above-mentioned strategic areas.[84][5]

By March 2014, antiretroviral treatment (ART) was provided to 116,421 patients from 73 treatment sites in the City region and TB treatment was provided to 26 305 patients in 208 TB clinics/treatment sites in the City of Cape Town municipality.[83]

In the Western Cape, a total of 15 498 VMMC procedures were performed in 2014/15 and this figure decreased in 2015/16 to 13 310. This was 9 589 short of the annual target of 22 899 the Department set itself.[85] Figure 6 below shows that the downward trend also exists at a national level as the amount of VMMC procedures done nationally in the public health sector since 2010 falls a long way short of the target set by the Department of Health.[86]

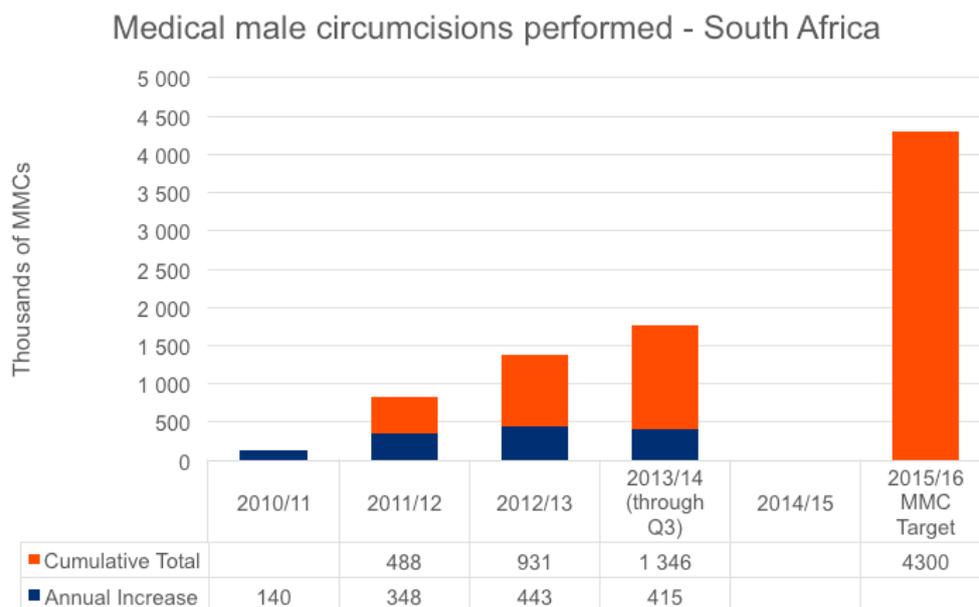


Figure 6: MMCs performed in the public sector from April 2010 to December 2013 vs. 2015/2016 targets

## 2.2 UNDERSTANDING THE CONTEXT (REFLEXIVITY)

As a researcher with more than 14 years' of experience in the facilitation of in-depth interviews, focus groups and quantitative survey tools, I am comfortable as an interviewer. However, looking back at the study and formally reflecting on my own skills, I realised that I still had issues I needed to resolve and keep track of. In addition to being trained as a researcher, I am also a Muslim who was circumcised as an infant, and I have formal training as an Imam and a family counsellor within a pastoral environment.

I am including three extracts from my fieldwork journal I kept during the qualitative phase of the study to illustrate these issues.

### *My Interpretive Crisis*

*I am a circumcised man, and so far all my participants in the project are men who have been circumcised or their partners who live with these men. I realised early that I am not a neutral participant in the research project. I have issues, concerns and opinions about male circumcision. I have desires for the project and what it will achieve or discover that are bound up with my views on assessment of the programme and what it should be or achieve, what is desirable and undesirable. I realised that I, in terms of qualitative work, was not an unbiased data-gathering tool. If I were to take the view of the traditional methodology texts on interviewing, in the light of the above points, I should be particularly concerned about my role in the research process as the main instrument of data collection. (Personal research journal, 10/4/2015)*

**“Faking” it?**

*I felt strange acting in the role of interviewer... because of my affinity with the participants. I didn't put this out in the open, and wonder if I should have? I felt as though it was a bit fake and not like the equal conversation that it could be if we just sat around and discussed circumcision issues and if I felt free to say more. I stuck to the guidelines according to the discussion schedule. I did probe, and I did give some personal examples and opinions. I restated and clarified, which, at the time I worried about whether I was “contaminating” the data. Also, having my own opinion and experiences and wanting to join in the discussion was an issue, so I did resist this and felt a little ‘fake’. (Personal research journal, 12/5/2015)*

My crisis stemmed from the fact that I did not find myself in a ‘neutral’ space when I facilitated the focus groups. Instead of managing the group discussions while looking for talking points and segues into the next discussion point, I instinctively found myself involved in the discussion. I had to remove myself from the conversation in order to facilitate in a coherent and somewhat neutral manner. I am naturally opinionated when discussing topics that I feel passionate about. I was worried that as a facilitator with much power in the group, I was going to influence the group dynamic and therefore skew the data. So when a contentious point was brought up that I had twenty responses to, I physically had to constrain myself and say: “Oh that’s interesting, what do you guys think about it?” My feelings of “fakeness” stemmed from those exchanges.

**My “Cognitive Baggage”**

*The problem is the grey areas in deciding what messages will work and at what frequency they should be transmitted. Is the main thing the ability for the man to understand the context of the messages or the extent to which the messages will influence his decision-making processes? And how does one assess those things? My idea of understanding and behaviour impact may be different from another person... We have clear performance criteria set for the project, but there are still grey areas, and many of the performance criteria such as partner communication and pain reporting, are subjective and open to interpretation. I have struggled with the conflicts in my role as assessor, supporter, communicator, listener, for both the participants and managing the project. I think I am too soft and I worry about being fair all round. (Personal research journal, 5/4/2015)*

In my experience over the past decade in assessing behavioural interventions, I have always been cautious about the drivers of behaviour-change, especially running a project within a community setting with much ‘noise’. I struggle with tying down the causal factor of the change, if there was any. Is it the content of the messages and what we intended it to be, or could it be something completely out of our realm of control? Perhaps it’s the nagging of the messages, or the motivation might be merely the fact that the person is in a research programme.

These three dilemmas forced me to ensure that I kept a tight reign on my own issues while I was analysing the data. The manner I used to safeguard the analysis was to have my supervisors review my conclusions and results I obtained from the data and whether my interpretations seem to be representative of their knowledge and beliefs. I also verified the results with quantitative data we obtained from the participants. During the data collection of Study I, I had the opportunity to triangulate the responses of the VMMC patients and how they viewed the role of sex in their relationships with their partners independently. I also tried to check for alternate explanations to the conclusions I drew from the data by using theoretical frameworks and in that way strengthened my interpretation. An instance of this, was when I looked at the transcripts of the focus groups in Study II that looked at the way VMMC patients managed pain and discomfort in the first week following the operation, I found much clarity in the way they expressed themselves when I viewed it through the multi-staged behavioural model such as the Health Action Process Approach (HAPA).

## 2.3 THESIS OVERVIEW

Table 3: Thesis overview

Study	Domain	Research questions	Study design & population	Timeline	Outcomes and conclusions?
I	PRE-TRIAL: Understanding the sexual behaviour of men in VMMC post-op period	<ul style="list-style-type: none"> <li>• Why do men in a predominantly Coloured community of South Africa, seek VMMC?</li> <li>• What were their experiences of the postoperative period in terms of penile recovery?</li> <li>• Why do men resume sex early after the VMMC procedure?</li> <li>• What sexual strategies do couples employ to negotiate the six-week recovery period?</li> </ul>	Focus group discussions  6 male groups (n=38) 3 female groups (n=14)	July – Aug 2014	<ul style="list-style-type: none"> <li>• Reasons for VMMC: religious injunction, hygiene, protection against STIs (not necessarily HIV).</li> <li>• Very little alternative non-penetrative sexual practices.</li> <li>• Pain and fear of any sexual arousal dominated first three weeks; sexual desire returned in last three weeks.</li> <li>• Sex seen as essential to maintain the relationship.</li> <li>• Counselling gaps in pre- and post-MC procedure.</li> </ul>
II	PRE-TRIAL: Developing and testing a participative, theory-based m-Health intervention	How can a mobile phone audio messaging intervention to task shift postoperative counselling on wound management and goal setting on safe sex be developed using a participative, theory-based methodology?	Content analysis, expert consultation, Cognitive interviews  Same cohort as Study 1 + 12 recently circumcised men	Aug – Dec 2014	<ul style="list-style-type: none"> <li>• Classic behavioural theories can and should be used to design modern m-Health interventions.</li> <li>• The target audience are the best source of messaging, ensuring that messages are culturally relevant to the recipient.</li> <li>• Patients prefer more salutogenic messages than experts.</li> </ul>
III	RCT Cohort study to improve safer sexual behaviour in the VMMC post-op period	Can an m-Health intervention based on mobile audio messages decrease the prevalence of penetrative sex among recuperating circumcised men during their six-week wound-healing period in clinics in the Western Cape Province, South Africa?	Randomised Controlled Trial 1,188 men recruited from 12 clinics in Western Cape	Jan 2015 – Jun 2016  Data unmasking and analysis: Aug 2016	<ul style="list-style-type: none"> <li>• A slightly larger positive effect in the Intervention Group than in the Control Group.</li> <li>• Alcohol use and anxiety associated with early penetrative sex.</li> <li>• Participants in the control group were less likely to engage in non-penetrative sex.</li> <li>• The intervention may have more effect on individuals with high risk propensity than those who do not.</li> </ul>
IV	NESTED IN STUDY 3: Assessing the usability of an m-Health platform	How did users rate the usability of the m-Health platform?	Questions embedded in follow-up questionnaire.	Jan 2015 – July 2016	<ul style="list-style-type: none"> <li>• Usability of the system ranked as 62.80 (SD 13.41).</li> <li>• Results from the focus groups suggest that most of users were positive about the messages.</li> </ul>

Study	Domain	Research questions	Study design & population	Timeline	Outcomes and conclusions?
			Focus group discussions  Experimental arm of Study 3 (n=597) + 5 focus groups with 25 recent patients		

Table 4 provides an overview of the four studies in the thesis and how they relate to each other.

## 2.4 STUDY METHODOLOGY

### 2.4.1 Study I

Study I was a retrospective study using focus group discussions with medically circumcised men attending the VMMC clinics in Heideveld and Mitchell's Plain in the Central Municipal Sub-Structure of the City of Cape Town municipality between February 2014 and July 2014. A contextualised interpretative analysis was used to develop a better understanding of how men and their partners feel about VMMC and sexual patterns around the wound recovery period. The interviews covered issues around the men's motivation to seek the VMMC procedure as adults such as how they experienced the medical procedure and what coping strategies they employed to manage the initial post-op period. The interview then explored how the men and their sexual partners managed a resurgent libido during the recovery period. The interview also investigated the cultural importance of maintaining a sexual relationship with a regular partner during the recovery period. During the interviews, information used in study II were also collected.

The study included six focus groups with men and three with women (Appendix 5). The sampling was done in conjunction with the VMMC booking officers at the two participating clinics. Male participants were randomly drawn from the VMMC theatre records of the last six months. The records consist of monthly lists of names, ages and contact details of VMMC recipients over the past six months. The fieldworker contacted all men on the clinic lists starting from the earliest month to the latest. Three men declined to participate at the initial contact point, citing time-constraints, and five men who initially agreed to participate, did not arrive at the group sessions. No information is available on them and other than citing time constraints, no other reason for not showing-up were given.

At the end of each focus group, the facilitator asked the participants if they would be willing to share the names and contact details of their sexual partners over the six-week postoperative period. Of the 38 men who participated, 26 men gave details of their partners. Reasons for not giving the details of their partners ranged from not knowing where their ex-partners are to the stated conviction that their partners would not participate in focus groups. No men reported having a male partner. The researcher contacted these partners by phone, which resulted in three focus groups with women (n=14) who were partners of men who had recently undergone VMMC. Seven women refused to participate (time constraints, personal reasons) and five women did not arrive at the sessions. No additional information is available on those who did not participate. After obtaining informed consent, male participants and their

partners were organized into gender-specific focus groups and interviewed between July and August 2014.

All of the participants had been residents in the community for most of their lives and were Coloured. The population of the clinic's catchment area is largely of the 'Coloured' race group and about 10-15% is Muslim. The study population reflected this demographic breakdown.

## 2.4.2 Study II

The purpose of this study was to develop a participative, theory-based, mobile phone audio messaging intervention attractive to recently circumcised men at voluntary medical male circumcision (VMMC) clinics in the Cape Town area in South Africa in order to task shift some postoperative counselling on wound management and goal setting on safe sex.

We developed an m-Health intervention using a staggered qualitative methodology: 1) focus group discussions with 52 recently circumcised men and their partners to develop initial voice messages they felt were relevant and appropriate; 2) thematic analysis and expert consultation to select final messages for pilot testing; and 3) cognitive interviews with 12 recent VMMC patients to judge message comprehension and rank them (Figure 6). The message content and phrasing was guided by the Theory of Planned Behaviour and the Health Action Process Approach.

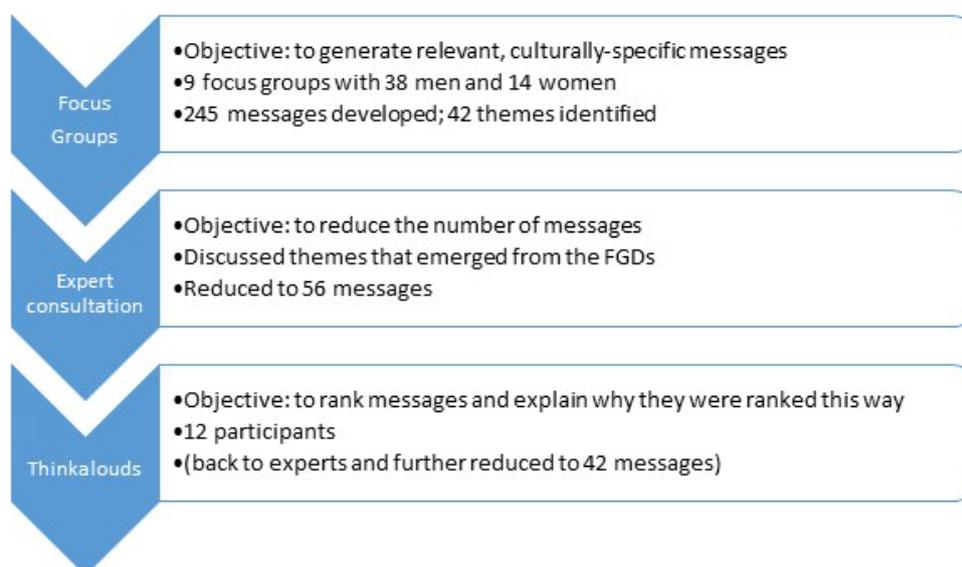


Figure 6: Steps to develop the content of the m-Health intervention

Study II used several participative, qualitative methods to develop the m-Health phone messaging system and their sequencing, placing emphasis on the user's needs and experiences. The first step was to use the focus group discussions with 52 recently circumcised men and their partners used in Study I to develop the initial messages they felt were relevant and appropriate. Before the discussions for Study I began, participants of these focus groups were asked to write down five messages they felt could have assisted them during this period. Focus group participants were given pieces of paper and a pencil, and on

their own, wrote down five messages, which they folded and placed in a bag that was circulated in the group. By asking the participants to develop the theme list, we were drawing out the relevant issues to improve motivation and reduce blocks to volition, as well as identifying key behavioural, normative and control beliefs. Additionally, information on the general acceptability of mobile messaging, generation of appropriate and relevant messages to recipients of VMMC during their six-week recovery period, and the acceptable frequency of mobile messages were collected.

The second step was the development of the final messages for pilot testing through thematic analysis and expert consultation with a Department of Health behaviour-change communication expert. As a first step, we looked at the raw list of messages generated by the focus group participants, then deleted incorrect, duplicate, and repetitive messages. We then grouped the remaining messages into themes and through inter-rater agreement, we decided on one or two messages representing each theme. At this stage, we adjusted several messages for technical correctness and added crucial but missing themes such as HIV prevention messaging. This occurred between July and October 2014.

The final step was to select 12 patients from the two participating VMMC clinics in Study I through the clinics' registrar offices. The two selection criteria were that they had to be 18 years old and above and they had to have completed the six-week wound recovery period in the previous month. They were invited to individual cognitive interviews between October and December 2014. The cognitive interview or "think-aloud" method was designed to track the processing of information through verbalisations while performing a task as it is involved in decision-making. These verbalisations are the actual clues to researchers to how decisions are arrived at.[87]

Cognitive interviews were conducted in the following manner: each message was read out to the participants and then tested for comprehension, such as repeating the message in their own words. We then probed for the participants' perception of the aim of each message. Following each section, participants were asked to reflect on the time period in the 42-day period for which this group of messages was designed. They were then asked to rank the messages in the group for appropriateness and clarity. The messages were put in groups of three to six messages for ranking purposes. Following the ranking exercise, using a think-aloud method, participants were asked to reflect on message grouping and whether there were any messages missing that could have made a difference, whether there were any unnecessary and inappropriate messages and to reflect on the reasons why they ranked the group in a particular way. This refines the contributions from step 1 improving the messages in terms of both the Theory of Reasoned Action and the HAPA.

### **2.4.3 Study III**

Study III enrolled patients who accessed twelve VMMC clinics in the South, Northern and Central sub-districts from January 2015 to April 2016 (Figure 7). Patients were eligible for this study if they were circumcised at the clinic on the day of recruitment, consented to

participating in the study, were 18 or older, possessed a mobile phone and were planning on being in the area for the six-week follow-up.

Study III utilised a two-armed, randomized, single-blind, controlled design (Pan African Clinical Trial Registry (PACTR201506001182385)). Only the patients were aware of the intervention assignment; while the clinic and research staff assessing patients, as well as statisticians, and authors were blind to the allocation.

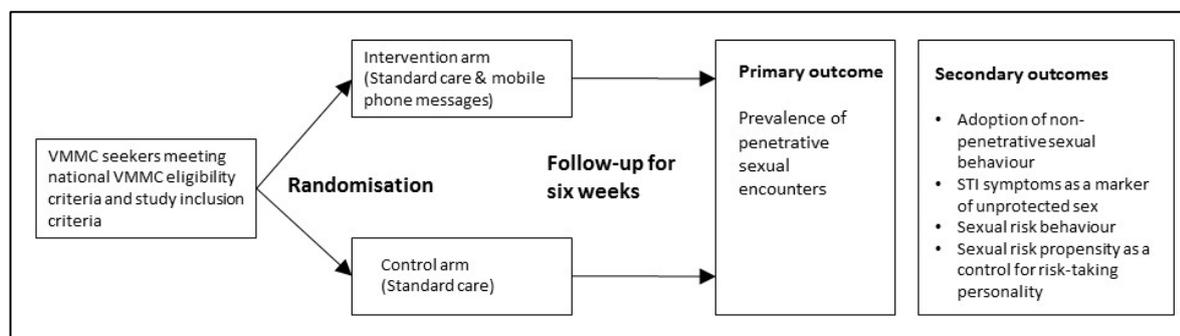


Figure 7: Trial design and outcome measures

**Randomisation:** The study utilised a random allocation rule method to generate a randomisation sequence. Through this simple randomising technique, we generated the random sequence (a 1:1 ratio in each group) for the entire trial using a computer-generated table of random numbers. The assignment sequences were placed in consecutively numbered opaque sealed envelopes and the study numbers were assigned consecutively to the participants as they entered the VMMC programme. Only the Office Manager had access to the sequencing master list ensuring adequate allocation concealment.

**Standard of care:** The standard of care offered by the provincial circumcision team consisted of the counselling session during the VCT procedure and a brief post-surgery counselling session, where they are advised on how to care for the wound and requested to go to their local clinic after two, seven and 14 days following surgery. They were reminded not to engage in penetrative sex until the mandatory wound-healing period of six weeks has passed. No further contact, beyond the three wound caring sessions, was provided unless the patient experiences complications such as swelling or infection.

**Intervention:** The intervention group received the standard of care, plus the intervention programme that consists of 38 audio messages that were delivered over the 42 days following surgery. The content and phrasing of the messages for the m-Health intervention were developed collaboratively with former patients and health promotion experts at the Provincial Medical Office as described above. The messages were then developed into short audio clips of 30-120 seconds each (in English and Afrikaans). The platform will contact the participant with the greeting: “Hello. This is the circumcision project with a message for you. Please enter your pin-number followed by the hash-key.” The system will then play the message to the participant. The call will be terminated with the following instruction: “Press 1 to listen to

the message again, press 2 to end the call. Good bye.” Based on the formative research, messages over the 42 days were divided into four periods:

Days 1-2: An intense two days of self-care messages (two per day). The theme of these messages revolves around coping with pain and recuperation.

Days 3-14: Mainly self-care messages (one per day). The theme is around strategies and practical tips on pain and wound management.

Days 15-28: Coping and inspirational messages (one per day). The theme is still around coping with the wound and inspiring them and encouraging them to include their partners in the recovery period.

Days 29-42: Inspirational messages (tri-weekly). The theme is around offering alternatives to penetrative sex and inspiring them to complete the period penile penetration-free.

**Study procedures:** The study participants completed self-administered paper-and-pencil baseline surveys and then returned to the clinic or other convenient location, after six weeks to complete a follow-up survey. Participants who were allocated to receive the audio messages were loaded onto the platform by the project manager who passed the participants’ cell phone numbers, pin numbers and dates of enrolment to the m-Health platform operator (a South African company Health Information Systems Program – HISP). The mobile system automatically called participants twice a day for the first two days, once a day for the next four weeks and on alternative days in the last two weeks. Using the last four digits of their mobile number as their password, the participant could listen to the message and, using their keypad, replay it if they did not understand the message. The platform was programmed to redial unanswered or busy numbers up to three times.

**Sample size:** We calculated that a sample size of at least 540 per arm, with a complete study sample of 1,080, would have 90% power to detect a 10% improvement in abstinence as found in previous studies, [17], [88]–[90] at 0,05 level of significance. The likely rate of loss to follow up was assumed to be 10%. Therefore the above numbers were adjusted accordingly and inflated by 10% to the effective total sample size of 1,188, or 594 per study arm.

#### 2.4.4 Study IV

Study IV was nested within Study III, but only included participants from the intervention arm of the main trial who answered additional questions on the usability of the platform at follow-up and some of whom were recruited to focus group discussions. The quantitative part of the study used the usability survey data from the follow-up questionnaire for its analysis. The qualitative part was based on a convenience sample of 25 participants from the intervention arm, constituting five focus groups. During the last two months of the study, whenever the participant completed the follow-up questionnaire and the study team quality-checked the completed survey, and found that the SUS scale was completed, they proceeded to recruit the participants for the usability focus groups. Using a convenience sampling method, 25 men who received the m-Health intervention and completed the follow-up survey were recruited in this manner. Five focus groups were then conducted at the clinics between

May and June 2016 with a total of 25 Coloured men from the Woodstock and Delft clinics. The participants' ages ranged from 18 to 54 (mean age 34).

**The SUS usability scale:** The SUS usability scale instrument was developed by John Brooke in 1986, as a reliable, low-cost usability scale that could be used for global assessments of systems usability.[91] This scale, originally developed for the industrial engineering field, has since been applied to a wide variety of products and services, including hardware, software, mobile devices, websites and applications in the medical field.[92] The SUS has been evaluated for validity, reliability, and sensitivity, although not in the current population.[91]–[94] This 10-item Likert scale instrument is administered immediately after the conclusion of the intervention programme and allows users to record their initial feelings and responses about the programme. The ten questions are:

1. I think that I could use this system frequently
2. I found this system unnecessarily complex
3. I thought this system was easy to use
4. I think I would need the support of a technical person to be able to use this system
5. I found the various functions in this system were well integrated
6. I found there was too much inconsistency in the system
7. I would imagine that most people would learn to use this system very quickly
8. I found this system very cumbersome to use
9. I felt very confident using the system
10. I needed to learn a lot of things before I could get going with the system

The instrument items have a range of 0–4 and the scores range from 0 to 100 which provides a clear estimate of overall usability of the intervention.[91], [92] The scores were calculated according to scale's guidelines.[91] This consisted of summing the scores on each of the 10 individual items. The values of the negative items 2, 4, 6, 8, and 10, were subtracted from 5 and the positive items were reduced by one and the final sum of all scores was then multiplied by 2.5 to get the overall satisfaction value out of 100. Scores of above 68 are considered to be acceptable or good while scores of 85 or above indicate a high level of usability or excellent score. Scores of 50 or below indicate poor or unacceptable usability.[95]

**Focus groups:** The discussion guide was designed to gather information from the men on their opinions on the frequency and content of the messages, whether they found the tool itself as intrusive and whether it had any impact on their behaviour and attitudes.

All interviews were conducted in Afrikaans, tape recorded and then transcribed and translated into English.

## 2.5 ANALYSIS

### 2.5.1 Study I

We used a contextualized interpretive analysis[96], [97] to analyse the data of this study. This method is similar to a phenomenological approach, but accords high importance to context in understanding what emerges. All the interviews were read several times by the researchers to obtain a familiarity with the material. On the basis of this familiarity, a set of themes were drawn out revolving around reasons for seeking VMMC, the experience around the procedure, the impact (short and long-term) of the procedure on relationships and sexual behaviours (Appendix 7). After my initial familiarisation of the interviews, I drew up the draft set of themes that was then circulated between the other two authors who used it as a basis to confirm or challenge the inclusion or exclusion of theme items through meaning and interpretation. We used these themes to code the interviews with the assistance of Atlas.ti. Once the provisional analysis had been done all the interviews were reread, as a validity measure, to check for contradictory findings, and if any information had been inadvertently excluded. In the analysis, we acknowledge that using a male interviewer could have impacted the validity of the responses of the female participants. We have attempted to take this into account in the analysis.

### 2.5.2 Study II

**Focus Groups:** After capturing and translating the messages generated by focus group participants, the list was cleaned and common themes were identified through use of thematic analysis using Atlas.ti.

**The health expert consultation process:** As a first step, we grouped the messages into themes and then deleted incorrect, duplicate and repetitive messages. Through inter-rater agreement, we decided on one or two examples representing each theme. Several messages were also adjusted to reflect technical correctness and missing themes such as HIV prevention messaging. This decision was guided by existing theoretical models of behaviour-change, including the HAPA Model. HAPA proposed a sequence of two continuous self-regulatory processes, a goal setting phase (motivation) and a goal-pursuit phase (volition). The latter is further subdivided into a planning phase, action phase, and maintenance phase. It is claimed that perceived self-efficacy plays a crucial role at all stages along with other cognitions.[68] For example, risk perceptions such as a recurring STI infection, serve predominantly to set the stage for a contemplation process to go for a circumcision procedure. This is true early in the motivation phase but do not extend beyond. Similarly, outcome expectancies are chiefly important in the motivation phase when individuals balance the pros and cons of certain consequences of their behaviours, but they lose their predictive power after a personal decision has been made. However, if one does not believe in one's capability to perform a desired action, one will fail to adopt, initiate and maintain it. Therefore the drive for the messages to be relevant to the patient's crisis-management in order to tap into personal convictions later on in the recovery period. The order and frequency of the messages

were guided by the recommendations of the focus groups, expert opinion and theory. This phase is essential to ensure the accuracy of the messages and their constructive interaction with the health services.

### 2.5.3 Study III

The statistical analysis plan was specified before the study was unblinded and was reported in the trial protocol published previously.[90] Analyses were undertaken on an intention-to-treat basis using SPSS[98] and Stata[99]. The primary outcome was the occurrence of penetrative sex at any time in the six weeks following the VMMC procedure. The primary analysis was to detect a difference in proportions using an unadjusted binomial test. Additionally, generalized linear regression models for the analysis of binary outcomes were used to study the effects of the intervention as well as possible synergistic effects taking potential confounders into account if necessary, such as age, religion, marital status, education, employment and depression. The effect of the intervention was expressed as a relative risk (RR); a 95% confidence interval (CI) was used for primary and secondary outcomes.

The secondary outcomes were i) the adoption of non-penetrative sexual behaviours in the six weeks after the procedure, ii) the prevalence of self-reported STI symptoms, iii) the perception of sexual risk behaviour, and iv) the self-reported level of sexual risk propensity (as a measure of risk-taking personality). The penetrative sexual resumption rate was assessed using Kaplan–Meier survival analysis techniques: for six-week follow-up data, resumption was assessed in participants who reported resumption of penetrative sex in weeks one to three, week four, week five and week six.

### 2.5.4 Study IV

**Focus groups:** Similar to the analysis methods of study I and II, I used content analysis on the transcripts of the five focus groups to judge how the user experienced the m-Health tool. As first author of this paper, and the person who worked closely with the participants and was present during the interpretation, I undertook the initial analysis while the other co-authors who were not part of the data-gathering phase assisted with the interpretation of the results.

**SUS usability scale:** Statistical analyses were performed using IBM SPSS Statistics 24 for Windows.[98] All outcomes were inspected for normal distribution using histogram plots including normal curves and normal probability plots, and Shapiro-Wilk tests, prior to selection of appropriate statistical tests. Descriptive statistics (mean with standard deviation (SD) for normal distributed outcomes, or median with interquartile range (IQR) for non-parametric outcomes) were used to describe the participant characteristics and all outcome measures. A factor analysis using a Principal Component Analysis extraction method with a Varimax rotation, Cronbach alpha coefficient and  $\chi^2$  were computed.

### 3 RESULTS

Below I summarize the main results of the four studies but also include some process information that may add to the understanding of the main results.

#### 3.1 STUDY I: UNDERSTANDING THE SEXUAL BEHAVIOUR OF MEN AND THEIR FEMALE PARTNERS AFTER VOLUNTARY MEDICAL MALE CIRCUMCISION

##### *Reasons for seeking VMMC*

In the first part of the study, we explored the reasons why men came to the clinics to be circumcised. Their primary motivation for seeking VMMC was threefold: it was either as a religious injunction; a strategy to prevent STI infection; or for health and cosmetic benefits. The men who converted to Islam as adults normally undergo the procedure within the first year after their conversion. The issue of free choice is very prevalent in this group. It appears that very few of the Muslim converts who came for VMMC do so out of personal choice. They usually came because of religious injunctions, or at the insistence of the spouse's family or Imam. The issue of coercion is also expressed by men who are 'forced' to go for a VMMC procedure by health service provider. This lack of choice might influence the male's sexual behaviour over the six weeks as well as his unwillingness to adhere to rules including the non-penetration rule. A dominant reason for undertaking the procedure among non-Muslim participants was the issue of hygiene. Both men and women named the presence and smell of dirt and semen trapped under the foreskin as motivation. Thus the motivation might not be seen as a specific attempt to reduce STIs or protect against HIV infection, but there may have been a subliminal link to becoming disease-free.

##### *Engaging in penetrative sex before wound healing*

Many factors propel men to engage in penetrative sex before the required six weeks have passed. [100] Literature shows that men in cohabiting relationships,[16] engage in penetrative sex before the recommended wound-healing period of six weeks has been completed. As described in the setting of the study population, couples live in fairly densely populated areas in small and cramped houses. Living together with very little interpersonal space, makes it difficult to avoid sexually laden situations, therefore arousal and the need for sexual gratification gradually builds. Additionally, men felt pressure from the socially-induced fear of failing to satisfy their partners and therefore not maintaining the harmony of the relationship. In line with previous findings, some men did report penetrative sex during this period.

##### *Sexuality and gender identities*

In our study, we looked at the perceptions of men and their partners on having to abstain from penetrative sex in the six-week postoperative period and the effect this had on their relationships and the forms of non-penetrative sex practised and other ways of stabilising the relationship. This question spoke directly to the importance men and women place on the role of sex in their relationships. Men saw sex as a physical act that confirmed their masculinity, their role in the relationship and a mechanism to maintain the relationship. Women, on the

other hand, saw sex more as an affirmation of the relationship and their role to provide for the ‘baser’ needs of the man.

#### *Penile function and sensitivity after VMMC*

There were both positive and negative comments on penile function and sensitivity depending on how old the respondent was (although the study was not designed to stratify by age). The younger participants were more positive. An exposed and desensitised penile gland meant that the man had more control over his ejaculations. Women also noted the ability of their partners to “hold out” longer after circumcision. The older participants were more negative for virtually the same reason. In this case however, diminished sensitivity meant lower responsiveness and that influenced erectile duration and quality during sex.

### **3.2 STUDY II: DEVELOPMENT OF THE INTERVENTION**

#### **Step 1: Generation of messages and key information on the messaging**

We ended up with a raw set of 245 messages that circumcised men and their partners felt would have had an impact on their behaviour and attitudes during the 42-day postoperative, wound-healing period.

#### *Themes*

The messages suggested by the focus group participants dealt with very practical themes, such as wound and pain management, the role of rest and family support, erection issues, how to stay healthy, when to resume sex, alcohol use, affirmation, sexual needs of partners, and condom use. These themes were then further grouped into phases and practical versus motivational messages. The selection of messages covered the dominant areas of the HAPA theory, ie, planning and its components of self-efficacy, goal setting and action (Appendix 7).

#### *The two-phase approach*

Our analyses indicated that participants divided the 42-day recovery period into a wound and pain management period (the first three weeks) followed by the adjustment period for the remainder of the period. The first phase was characterised by practical issues, such as wound and pain management, while the second phase was dominated by motivational and planning issues.

#### *Salutogenic nature of the messages*

A strong preference towards positive and inspirational messages and not messages that emphasised disease and negative consequences were suggested by the groups.

#### *Frequency of messages*

Participants were wary of unsolicited and invasive messages and preferred a clear end date of the programme.

## Step 2: Expert consultation

Together with the expert from the Provincial Department of Health, we reduced 245 messages to 56, by removing the duplicates and similar themed messages. These decisions were made with extensive knowledge of local knowledge of the population and local conditions, safe-sex and behaviour-change. Table 7 shows the full set of themes by phase once all the messages were combined into a reduced set of thematic constructs, while remaining responsive to community felt needs.

Table 7: Themes and messages by phase after expert consultation

Phase	Themes	Examples of Messages
1	Inactivity and rest	<i>Rest! This will help with the wound healing.</i>
1	Role of the clinic; Wound management	<i>Go back to the clinic after two and seven days so the dressing can be replaced and the wound can be checked.</i>
1	Wound management; hygiene	<i>Use lukewarm water to wash the wound every day. Keep the dressing dry.</i>
1	Wound management; Erection issues	<i>Check for any skin tightness when you get an erection.</i>
1	Role of the clinic; Wound management	<i>If there is pus coming out of the wound, go to the clinic.</i>
1	Pain management; Medication	<i>Don't be brave! Take pain tablets to relieve the pain</i>
1	Wound management; Partner/Family support	<i>Are you having a difficult time? Talk to someone you love. They will understand.</i>
2	Self-efficacy & affirmation; Goal setting	<i>Want to be healthy? Look after yourself.</i>
2	Self-efficacy & affirmation	<i>You can do it!</i>
2	Partner/Family support	<i>Make sure you talk to your partner</i>
2	Self-efficacy & affirmation; Motivation	<i>Did you look after your penis today?</i>
2	Goal setting; Healthy living	<i>Regular exercise and healthy diet are essential</i>
2	Wound management; Erection issues	<i>Get rid of that painful erection by urinating frequently</i>
2	Early resumption of sex	<i>Having sex too early, will just set you back!</i>
2	Early resumption of sex; Alcohol consumption	<i>Be aware of alcohol. It impedes your judgement</i>
2	Safe living; Condom use	<i>Remember that circumcision does not provide 100% protection</i>
2	Motivation; Goal setting	<i>No sex or masturbation for six weeks!</i>
2	Non-penetrative sex; Sexual needs of partner	<i>Find ways to please your partner without using your penis</i>
2	Non-penetrative sex	<i>Loving is not about sex only!</i>
2	Self-efficacy & affirmation; Motivation	<i>You are the best!</i>
2	Motivation; Goal setting	<i>Regular condom use, knowing your HIV status and keeping to one partner is the recipe for an HIV-free future.</i>

## Step 3: Cognitive interviews

We recruited twelve participants who engaged intimately with the messages and generally confirmed the set of themes proposed by the previous step, except for the fact that former patients rejected some of the messages that were worded too technically or 'preachy', thus reaffirming the initial focus groups' preference for more salutogenic messages. Their interaction with the messages originated from their own experiences during the wound-healing period and confirmed the elements of motivation and volition as proposed by the HAPA model. We separated the six-week period into three two-week periods for ease of rating and discussion.

**Messages for weeks one and two:** This period was dominated by pain and wound management themes and towards the end of this two-week period, the patient's support structure is also given priority. The participants also recommended that the frequency of phone messages to patients should be twice a day at the beginning of the period, tapering to once a day after the first two days, to provide additional support for the days following the operation.

**Messages for weeks three and four:** The messages in this period reflect the changing priorities of the participant. The wound is for all intents and purposes healed and the patient is going through a period of how to adjust to this new body part, not only sexually, but also aesthetically and the way it felt.

**Messages for weeks five and six:** The high scoring messages in this period revolved around alternative sexual activity "*Loving is not about sex only!*" and validation, such as "*You lost the skin! Can you feel the difference?*" and looking-ahead messages, such as "*You are planning for your future*".

See Appendix 4 for the complete m-Health intervention messages.

### **3.3 STUDY III: EFFECTIVENESS OF THE INTERVENTION (RANDOMISED CONTROLLED TRIAL)**

Between January 2015 and August 2016, 1,670 VMMC patients at twelve clinics were screened for inclusion into the study. 476 (28.5%) participants were excluded from the study prior to randomisation for the following reasons: 201 did not meet the inclusion criteria (142 patients were too young and 59 had no mobile phone), 216 were medically excluded from the VMMC procedure by the VMMC team, 48 were not interested in the study and 11 were excluded for other reasons. 1194 men (71.5%) were recruited into the study and randomised. After enrolment, 597 participants were randomised to each of the intervention and control arms. (See Appendix 11 for Consort diagram)

At the 42-day follow-up stage, the study could not collect data from 117 participants (9.8%). We followed up telephonically with this lost-to-follow-up group with a shortened questionnaire and we managed to obtain data from a further 61 (29 Intervention and 32 Control) participants. The data obtained from this cohort was incorporated into the main dataset. The remaining 56 loss-to-follow-up participants (4.7%) had similar pre-randomisation characteristics (Appendix 10). The follow-up study found that 31 participants were too busy to participate and 25 participants had moved from the area.

We found that exposure to the audio messaging system led to a modest decrease in the occurrence of penetrative sex compared to a control group who only received standard face-to-face care (28% vs. 32.3%), although the difference was not significant. We also found that the reporting of penetrative sex within the six-week recovery period was associated with higher alcohol use and anxiety levels. We found a statistical trend suggesting that the presence of sexual risk factors such as the presence of at least one STI symptom and a self-perceived HIV infection risk, as well as a high sexual risk propensity, self-rating were

independently associated with the higher incidence of penetrative sexual encounters during this period.

We also found that the level of sexual risk propensity had a greater effect on those who did not receive the intervention than those who did. The relative risk for sexual risk propensity was 3.91, which was the increase in risk for sexual activity with a one unit increase in propensity score for the control group. The interaction risk ratio was 0.197, which is the difference in risk ratios between the intervention and control groups ( $p=0.027$ ). This means that the effect of the sexual risk propensity on early resumption of penetrative sex in the recovery period was different for the intervention and control groups. In the control group risk propensity increased the participants' likelihood of having sex, while in the intervention group there was minimal influence of risk propensity at baseline on early resumption of sex.

We found that participants who did not receive the audio messages had 26% less risk of engaging in non-penetrative sexual encounters in the post-op period compared to patients who received audio messages. This finding was statistically significant ( $p=0.009$ ). While controlling for self-reported one or more penetrative sexual encounter in their recovery period and reported high sexual propensity risk scores, patients who did not receive the audio messages were 26% less likely of reporting one or more non-penetrative sexual encounter in their recovery period compared to patients who received audio messages. This finding was statistically significant ( $p=0.013$ ).

We also conducted a survival analysis on the time to the resumption of penetrative sex of the participants and found that there was no significant difference between the two groups (Log rank: 2.77,  $p: 0.096$ ). The mean time to sexual debut in the intervention group was 5.81 weeks and in the control group it was 5.8 weeks. Amongst those who reported penetrative sex during the six-week recovery period, 48.2% of the intervention group and 50.9% of the control group engaged in sex between week three and week five of the recovery period. The remainder reported re-engaging in penetrative sex in week six.

### **3.4 STUDY IV: MEASURING THE SATISFACTION AND USABILITY OF THE M-HEALTH INSTRUMENT**

#### **Message delivery**

The mobile phone monitoring reports of the total number of calls that went out to all patients in the intervention arm indicated that 99% of scheduled calls went through, and 87.71% of these calls were received and acknowledged by patients (see section 4.2 below).

#### **Usability scale**

The SUS showed a good reliability and internal validity in the population.

The average SUS score for the whole group was 62.80 (SD 13.41) indicating a marginal satisfaction rating across these m-Health system users. However, wide variations in scores existed with a low value of 27.5 and high score of 87.5 with a range of 60-points. The spread

of the scores shows that 50% scored 60 points and below and the top third percentile scored 75 points and below.

On individual level, 207 (38%) participants rated usability over 70%, which means that the technology will have good to excellent chances for acceptance in the field, whereas 93 (17%) participants scored SUS below 50 % which indicates an intervention that will probably have usability difficulties.

We did not find any significant differences in the participants when we compared the usability rating scores with the main demographic variables of the men in the study. Foreign language users (86.0, 13.99) and room and garage dwellers (79.39, 13.02) had slightly higher usability scores than their counterparts.

### **Focus groups**

The results of the focus group analyses are presented by the four topics explored in the discussions:

**The frequency of the messages:** Participants generally did not have an issue with the frequency of the messages because everyone knew what the programme was about.

**The content of the messages:** Most of the participants appreciated the narrow focus and contextual nature of the messages.

**The perceived intrusiveness of the tool:** The messages were short and infrequent enough to have the least impact on the participants' lives. There were some time clashes.

**Reported impact on behaviour and attitude:** Most participants felt that the messaging system had a positive outcome on their behaviour and attitudes, as they were dealing with the recuperation and health issues in the recovery period. The relevancy and frequency of the messages acted as judicious reminders to the recovering men, forcing them to reflect and plan their behaviour. As effective as the men found the programme, some of them did not adhere to the messages.

## **4 PROCESS ISSUES**

### **4.1 FRONTLINE STAFF AND THE INTERVENTION**

This study was designed to complement the excellent work done by dedicated frontline healthcare staff working in very difficult structural circumstances within the healthcare system. This self-care m-Health intervention aimed to add to the standard of care counselling regime that the VMMC patients receive in the VMMC clinics. It was not designed to substitute the counselling the patients receive before or after the surgical procedure in the clinic. Its primary goal was to pick up the participant from the time he leaves the VMMC clinic to the end of his 42-day wound recovery period. Therefore, from a systems perspective,

this intervention was designed not to interact with the healthcare frontline staff in the VMMC clinics, but rather, complement and shore up the counselling aspect of the VMMC care, after they leave the clinics, with the purpose of keeping the VMMC patient safe over the six-week recovery period.

Comments from my half-time seminar encouraged me to question the role and attitudes of healthcare staff on our intervention. Although we had discussed the goal and relevance of the intervention with leadership at the Provincial Department of Health, we had not systematically interviewed health care staff. In February 2016, I interviewed Dr Shaheen Hartley, the Head Surgeon of the VMMC team in the Central and Southern Sub-structure for the duration of the study period. I asked him what he thought of the intervention and the goals it set for itself.[101] He was very complimentary of the intervention and went into detail of the emergency cases they were getting with torn stitches and penile infections within the first three weeks following surgery and penile tearing during the last three weeks of the recovery period. He acknowledged that the current system was geared more towards the surgical aspect of the VMMC process rather than what the patient does afterwards. He said that in the beginning of the VMMC drive after 2010, the typical patient who came in for circumcision were self-motivated and therefore more aware of the processes that needed to be completed. These were typically older men who wanted to be circumcised in the first place, therefore the health talk on the day of the surgery was easy and the safety points that had to be covered were transferred much easier, because these men listened. He felt that some difficulties crept into the system when the numbers of the traditional self-motivated patients started to dip and DoH appointed community mobilisers to actively recruit men in the communities to be circumcised. Dr Hartley felt that this recruitment process brought a different type of men into the process. They were usually younger, mostly unemployed and, in many cases, had not really thought the circumcision process through. In his opinion, these men had a more difficult time on the day of the surgery. Many of them were under the impression that the surgery was “just a minor inconvenience” and they could go back to their busy and active lives. He estimated that 90% of the emergency comebacks were that of men who simply did not adhere to anything they were told to do. He suggested that we not only target no sex behaviour, but expand it to include all the wound-recovery messages that are given before surgery.

I also participated in a feedback workshop at the end of the fieldwork phase with nursing staff at Elsie's River Clinic in the Northern Sub-structure. They had the same comments as that of Dr Hartley made. Additional comments were that they sometimes had difficulties with our study in the clinic as they had to wait for the patients to complete the questionnaires which they felt was too long and were putting the patients under stress. When prompted how often this occurred, the nurse conceded that did not happen frequently. The general staff that received the men on days two, seven and 14 in the wound recovery section, did not know about the study nor did they hear anything being said by the patients about the study. When asked whether they reinforced any behavioural messages at those three consultation sessions,

the answer was negative because they only concentrated on wound management. They also supported the idea that the messages should be more wound-management-centred.

## 4.2 FIDELITY OF THE INTERVENTION

A high level of intervention fidelity was maintained during the trial. The mobile phone monitoring reports of the total number of calls that went out to all patients in the intervention arm indicated that 99% of scheduled calls went through, and 87.71% of these calls were received by participants (Table 5). In addition, at an individual level, the participants in both arms who did not present at the follow-up data collection point were contacted telephonically and asked about the reasons for the drop out. In addition, 62 of the 117 lost to follow-up participants completed a shortened questionnaire around the main outcome variables. There were no reported adverse events associated with phone use, and using the Systems Usability Scale, the participants scored out a range from 0 to 100, a mean of 76.72 (13.223).

Table 4: Percentage who accessed intervention messages

Day	Message	Accessed (%)	SD
1	rest helps with healing	92.1	0.270
1	rest helps with healing 2	85.4	0.353
2	keep appointment schedule	96.3	0.189
2	bath. Keep dressing dry	76.5	0.424
3	lukewarm water	87.6	0.330
4	talk to someone	81.6	0.388
5	no pulling or scratching	92.5	0.264
6	clinic: meds not working	72.9	0.445
7	clinic: difficult urinating	85.1	0.356
8	clinic: pus out of wound	77.7	0.416
9	clinic: fever	80.2	0.399
10	clinic: abdomen pain	91.5	0.280
11	skin tightness during erection	85.4	0.353
12	look after yourself	87.8	0.328
13	clinic: bleeding	86.9	0.337
14	VMMC not 100% protection	91.0	0.287
15	involve partner in recovery	86.4	0.343
16	think before you do	93.7	0.250
17	just a few weeks more	89.7	0.310
18	early sex will set you back	82.6	0.380
19	please your partner	93.0	0.256
20	exercise and diet	91.0	0.287
21	you can do it	94.3	0.232
22	be proud of yourself	98.2	0.135
23	early sex will set you back 2	85.4	0.353
24	urinating helps with erections	88.9	0.314
25	take pain tablets to relieve the pain	86.3	0.345
26	look after your penis	95.3	0.212
27	no sex or masturbation	88.9	0.314

28	be aware of alcohol	84.4	0.363
29	listen to your partner	84.6	0.361
30	early sex will set you back 3	85.8	0.350
32	Loving is not only sex	87.8	0.337
34	You did it	86.9	0.287
36	Target healthier body	91.0	0.343
38	Don't need penis for loving	86.4	0.250
40	Restraint will be rewarded	93.3	0.310
42	HIV-free recipe	89.3	0.337

## 5 DISCUSSION

This discussion is divided by what I see as the most important findings and contributions from the study. This is followed by a discussion of the ethical and methodological considerations that the reader should bear in mind.

### *VMMC is practiced for different reasons*

Circumcised men and their partners in the Coloured communities of Cape Town had a variety of primary motivations for undergoing VMMC. Those who did it because others required/requested it (due to conversion to Islam or because of frequent STIs), spoke about external coercion that was either social in the case of religious conversion, or medical in cases of STI infections. This externalisation of choice could have a substantial amount of influence on how they approach the strict treatment regime especially during the first two weeks into the recovery period, and the restrictions on penetrative sex in the last part of the recovery period.

Nobody in our study explicitly said that HIV prevention was the reason why they wanted to be circumcised, but both men and women cited hygienic reasons such as the presence and smell of dirt and semen trapped under the foreskin, as a strong motivation to be circumcised. Cleanliness is often seen as being the opposite of diseased,[102] so there may have been a subliminal link to becoming disease-free. Responding to the direct question of whether they thought that VMMC was a protective barrier against HIV infection was a good thing, most of them responded positively to the idea, although we surmise that the HIV infection barrier was a 'nice-to-have' rather than to motivate as a primary reason. With a rising HIV prevalence in the Coloured population, and the study participants' stated aversion to regular condom use,[103] there remains a heightened risk to HIV and other STI infections. The stigmatic phenomenon of ascribing the HIV epidemic as a 'Black' disease or a disease that is ravaging everywhere in South Africa except in the Western Cape, serves to perpetuate undue risky behaviour within the community. The fact that they really do not see themselves at risk of HIV, is a particular source of concern, given the generalized nature of the epidemic in the Coloured population. On the other hand, in a study conducted in 2012 in urban Swaziland, they found that male circumcision fostered a protective behaviour-change in the patients and found them with a more responsible attitude towards safe sex and easier condom use.[100]

*Sex is important for couples from a gender identity perspective*

The focus group discussions indicated that both men and women in this population group saw the sexual act, not only as a biological need, but also as a social tool in relationship maintenance. Although men were perceived to be more sexual than women, both viewed sexual activity as a measure of who they are in terms of gender, as well as using it to gauge marital success. This is an important point to remember for programme developers when they look at how couples negotiate the six-week abstinence period, particularly the last two weeks when the penile wound has healed to the extent that it does not present a medical barrier. Non-penetrative sexual activity, such as rubbing, mutual masturbation, kissing or cuddling are used as alternative to penetrative sex, but there was a general feeling among male participants that it was a poor substitute for 'real sex'.

***Ensuring the relevance of messages requires participative methods***

The study showed us one method to compile a relevant programme is to directly engage men and their partners in iterative discussions about message design and delivery, and involve them in the development of messages so that messages are relevant and meaningful for the recipients.

A few studies have utilised a multi-phased approach with a strong target group participation to construct and develop m-Health messages. Ybarra and team (2015) designed an m-Health HIV prevention program for adolescent gay, bisexual and queer men, by taking the message development through five iterations with target audiences contacted in the first phase to test acceptability of the messages and during the last phase with beta testing. They found, as in our study, that participants preferred positive and friendly content that does not sound that it is delivered by a teacher.[70] Similarly, Jensen and colleagues (2016) explored obese adolescent participants' perspectives related to weight management messages, and they found enthusiasm for SMS messages that were brief, positive, encouraging messages that had a 'natural' tone and made specific reference to the teen demographic, as a strategy to support weight loss efforts among these participants.[104], [105] Another m-Health weight management programme conducted by Hindle and her team in 2013 also using a multi-stage youth participatory approach, found similar results.[72] The main difference of our study to the ones mentioned above, is that the source of the messages in our study came from the target audience as opposed to researchers and experts. This resulted in a fairly good usability rating in our study. Although we cannot know if usability would have been lower without participation from former patients and their sexual partners, action research theory strengthens our argument that meaningful interventions are co-developed with the target group.

*Using behavioural-change theories can strengthen messaging*

There is a paucity of studies that use behavioural-change theory in the development of messages. To develop and test messages to influence the knowledge, attitudes and behaviour of adolescents on nutrition and physical activity, Hingle et al (2013) used a 3-phased youth-participatory approach. The first phase was the identification of content and initial message development by content experts and experts in the field, the second was message testing and refinement that was done with a sample of the target audience and the last phase was pilot-

testing of a message delivery protocol.[72] Other similar studies by Bock [71] and Yberra [70] concluded that partnering with the target population in the message development phase is critical to ensure that a salient and relevant final product is produced. The salutogenic versus the pathologic nature of the messages has also been shown as a deciding factor in the rate of acceptance of the m-Health interventions.[106], [107]

Our study used a participatory approach to take the opinions of the target population in the development of the messages and the frequency of messages into account. The first phase of involvement was at the generation of the messages, followed by the reflection of expert opinion on these messages. Finally, a group of recently circumcised men was used to test a cleaner and more theme-centred set of messages for relevance and impact.

The focus groups told us that the recovery period of 42 days following the VMMC procedure is not a homogenous period. Rather, we had to think of it as a series of progressive phases flowing naturally into each other. The first phase is one of survival. From the purely physical pain and trauma to the only issue in the early phase, which is wound management healing. The next progression is that of adjustment, to how their circumcised penis was looking and feeling, and realigning their attitude towards this new feature in their lives. The last phase is dominated by an external adjustment to physical movement and sex drive. The content of the messages needed to reflect this continuous movement through the 42 days. The progression of the messages followed this pattern, from the more practical messages, centred on pain and wound management, to more inspirational and “planning-ahead” messages at the end of the recovery period.

We found that applying this theoretically informed approach carefully, resulted in message content that was consistent across different recuperation phases. We made sure that the messages fitted into the existing standard of care regime offered by the clinic, from the three sessions to check the wound and change the dressing, to encouraging them to use clinic services in case of medical emergencies.

#### *Participants are more interested in salutogenic messages*

A compelling finding of the study was that there was a strong consensus that salutogenic and caring messages have a better impact on behaviour-change than pathological ones. The salutogenic model is useful for health promotion as it provides a clear direction and focuses on the entire person in relation to the disease.[106] We found that the messages that health communication experts considered as essential knowledge and skills for circumcised men to navigate their wound-healing period successfully, such as standard condom-use and HIV prevention messages, scored consistently low in desirability and impact. This could be because the messages were addressing irrelevant issues of the target audience as most of the participants went to be circumcised for reasons other than HIV prevention. Another reason for their low scoring could be that there is a perceived over-saturation of this type of messages and the low scores merely represents a natural push-back.

#### *The voice message system did not have a significant effect on penetrative intercourse in the recovery period*

To our knowledge, this was the first randomised trial to evaluate an audio messaging m-Health system to improve postoperative counselling to recovering VMMC patients. We

found that exposure to the audio messaging system led to a modest decrease in the occurrence of penetrative sex compared to a control group who only received standard of care (28% vs. 32.3%), although the difference was not significant. This non-significant result could point to the fact that m-Health strategies cannot be used in isolation to effect behaviour-change, suggesting that they must be used in conjunction with other counselling and support programmes to safeguard men's health during this recovery period.

#### *The intervention may be effective for high-risk VMMC patients*

Our study showed a clear interaction effect between the probability of engaging in sexual activity early and sexual risk-taking personality of the control group who did not receive the m-Health intervention. Thus, the intervention seems to have been effective in reducing risk-taking behaviour amongst men with higher risk at baseline. This indicates that if VMMC patients were screened for risk-taking behaviour at the pre-operative phase, the intervention could potentially be offered only to those who display a sexual risk-taking personality and that could prevent even riskier behaviour than what we saw amongst those who received the intervention.

#### *Early resumption of sex in the recovery period is a fact*

About one-third of the study population resumed sex before the WHO-recommended time limit of six weeks and nearly 50% of those who reported engaging in penetrative sex during the recovery period had sex before week five. Amongst those who reported penetrative sex during the six-week recovery period, 48.2% of the intervention group and 50.9% of the control group engaged in sex between week three and week five of the recovery period. Thus, the issue of early resumption of sex, as indicated by previous studies in other countries in the region, is a fact in South Africa and still needs to be addressed.

#### *The intervention platform had medium to low usability score*

Our m-Health platform was rated medium to low on a usability scale, with a scale mean of 62.80, which is below the industry-standard usability mean score of 68.[94] The low score confirms that the intervention needs to be adjusted and improved. On the other hand, the qualitative responses indicated that participants generally received the frequency of the messages positively due to their pre-knowledge of the rate of the message delivery before the programme started. The men also found the use of the technology easy to cope with. The messages were generally perceived as relevant because we designed it in such a way that the timing of their delivery coincided with specific health or recuperation issues that the men were grappling with. This relevancy-rule matches other m-Health intervention literature that proposes that the content of the intervention needs to be better adapted to suit a wide variety of users in order to facilitate a wider usage for a larger number of users.[108]

## **5.1 METHODOLOGICAL CONSIDERATIONS**

We spent much effort and time during the project's planning stage to ensure that our study was rigorous, valid, reliable and actionable. We found it markedly easier to apply these expectations to the quantitative phases of the overall project, but more difficult for the qualitative stages.

### 5.1.1 Qualitative data

In this section, I will outline the steps we took to ensure an acceptable level of trustworthiness[109] of our qualitative data. I will use the following criteria set out to evaluate qualitative research: dependability, credibility, transferability and confirmability. [109][110][111]

**The dependability of the data:** This refers to the stability of the data from the time it was collected in the field to when it is synthesised and interpreted in study reports and articles.[111] Schwandt et al. recommends the following strategies:[112]

- *An audit trail:* We have kept detailed records of all focus groups and interview transcripts, observational fieldwork notes, fieldwork activities and administrative forms, to allow an auditor to conduct a thorough audit trail. These records are available on request. (*also see:* Confirmability)
- *Stepwise replication:* All of the qualitative data was analysed by myself, but all of the data was checked by the two principal investigators.
- *Triangulation:* This strategy was used in Study I where we collected data from the VMMC patients and then from their partners using identical questions and probes. In Study II, we retested the data taken from the focus groups with a cohort of single in-depth interviews. (*also see:* Credibility)
- *Peer examination/peer debriefing:* I received feedback on all the raw transcripts, coding frame and interpretation by the two principal investigators of the study. The content expert from the Department of Health also provided valuable feedback in Study II.

**The credibility of the data:** Credibility is defined as the confidence that can be placed in the truth of the research findings.[112] The credibility criterion looks at whether the conclusions the study makes is congruent with the original data collected from the participants in the field.[112] The following strategies are recommended:[109]

- *Prolonged engagement in field or research site:* I worked with the participants in the field for two years and understood the circumstances and the environment the study participants came from. The fieldworkers were from the same area, they spoke the same language and all of them had extensive fieldwork experience beyond the study.
- *Use of peer debriefing:* I had regular feedback sessions with the PIs where I presented fieldwork reports for feedback to improve the quality of the data. The study also had a mid-study auditor who looked at the data collection methods and process, data management, transcripts, data analysis procedure and research findings. The researcher also presented the data to the DoH team who also provided feedback to the study.
- *Triangulation:* (See the dependability strategies above)

- *Member checks*: I only used this strategy in Study II when I tested the complete message system with the 12 VMMC patients.
- *Negative Case Analysis*: Going through the interviews again revealed few contradictions with the analysis. Where minor conflicts occurred these were reformulated.
- *Persistent Observation*: I was assisted in understanding the nuances of the participants' remarks and observations by my research experience with this population and in this context, and the fact that I am of the same ethnic background.

**The transferability of the data:** This strategy refers to the degree to which the results of qualitative research can be transferred to other contexts or settings with other respondents.[113] The following strategies are appropriate:[109]

- *Provide thick descriptive data*: This strategy required me to expand and explain all the research processes of the study. From the data collection and the context of the study to production of the final report. The thick description helps other researchers to replicate the study using similar conditions in other contexts or settings. The research team has successfully transferred this programme to a similar study in Bloemfontein, Free State Province.

**The confirmability of the data:** This strategy refers to the degree to which the results of the inquiry could be confirmed or corroborated by other researchers. There is only one strategy recommended:

- *Practice reflexivity/reflexive journal*: I have kept a fieldwork diary throughout the fieldwork and analysis phases, documenting personal reflections in relation to the study such as ethical dilemmas and 'aha' moments that arose during the process of the investigation.

By following these guidelines and strategies, I feel that I have fulfilled and completed all the strategies to ensure that my qualitative study remains trustworthy.

### 5.1.2 Quantitative data

#### External validity

*Study population*: Participants in the study are no different from the general population they come from in the communities located in the catchment areas of the healthcare clinics. We recruited all the types of VMMC clients: walk-ins, clinic recruited and community mobiliser recruited. The study's eligibility and exclusion criteria were designed in such a way to retain all men 18 or older who indicate at the pre-counselling session that they a) possess a mobile phone, and b) consent to participating in the study.

*Study decliners:* Out of the 1670 VMMC patients at 12 clinics who were screened, only 1194 men (71.5%) were recruited into the study and randomised. 476 (28.5%) patients were excluded from the study (Appendix 11) for a variety of reasons. The demographic features of the 48 (2.9%) eligible participants who declined to participate in the study were similar to the main study cohort. (Appendix 12)

The advantage of a controlled study is that both the control and intervention groups were interviewed an equal number of times so there would not be a Hawthorne effect. There may have been more motivation to change their behaviour simply by the act of receiving phone messages (as opposed to the content itself) but if this changed behaviour then it was an acceptable public health outcome.

### **Internal validity**

The study was conducted with rigour and sought a high degree of internal validity by the random assignment of the intervention, with pre-specified blinded analysis. The performance of the intervention was monitored over the duration of the study period and the fidelity was high.

*Missing participants:* We compared the demographic profiles of our loss-to-follow-up cohort and I did not find significant difference between them and participants who completed the study. (Appendix 10)

*Item reliability in the SUS scale:* In study IV, we tested the internal reliability of the scale items and obtained an overall Cronbach's alpha score of 0.648. Three factors loaded prominently (Eigen value >1) and explained 67% of the variance and revolved around the usability and learnability of the scale.

## **5.2 ETHICAL CONSIDERATIONS**

The three fundamental principles of research ethics – Respect, Beneficence, and Justice – are upheld in this study through the following processes: The design and use of an ethically approved informed consent form, the adherence to a completely confidential enrolment procedure and documentation system, and all research staff went thorough ethical training and Good Clinical Practice certification.

The study had to navigate several ethical issues. The first one was its target audience in Cape Town. It used members of the Coloured community at the exclusion of members of the Black community who have traditionally been pegged as the higher risk to HIV infection. The reason for this inclusion criterion is that the majority of Blacks in the City of Cape Town municipality area are from the Xhosa-speaking community who practice male circumcision in traditional ceremonies and thus do not seek it in large numbers from clinics. For the purpose of the study, the study population being essentially homogeneous worked in the study's favour. Once the intervention's effectiveness has been proven, cultural adjustment could be made to the content of the messages to target this grouping.

Another ethical dilemma was that one of the exclusion criteria included not having a mobile phone and the sexual risk profile of lower economic status communities is well published. Also, due to legal and logistical reasons, the study also excluded persons under the age of 18, where research has shown that sexual risk behaviour starts at an earlier age. The study found that the possession of a mobile phone as an inclusion criterion is central to the delivery of the m-Health intervention. Studies have shown us that the penetration of mobile phones, especially in this population demographic, is nearly universal. Our study reported that out of the 1125 participants approached to participate on the study, we only had to exclude 16 participants for not having a mobile phone. With regards to the age limitation, we acknowledge that risk to HIV and other STI exposure is not restricted to a legal-age status, but the ethical procedure for recruiting minors would have necessitated an additional tier in the study population.

The study proposed, as per RCT conventions, to introduce the behaviour intervention to only the randomly selected intervention group with no plans to offer it to the control group for obvious logistical reasons. It remains, however, an ethical dilemma that a group with the same risk profile as those receiving the intervention were denied access to it. This presented a regrettable ethical issue as the intervention was time-bound and it was not possible to offer it to the control group after exiting the study since they would have already passed the six-week message period.

The last ethical issue the study had to grapple with is that participation incentives were given to the participants at the baseline assessment phase (\$7) as well as when they come back for the post-intervention assessment (\$10). The question being raised was that, with the study being conducted in a generally poor community, whether the incentive constituted an undue pressure for study participants to participate. The challenges of incentivising participants for participating in research are very well documented and debated. We followed GCP guidelines on this matter and we made sure that the participants were very well informed of their rights when they were recruited into the study. The ethics committee of the University of Stellenbosch determined that the amount was not coercive in this setting.

### *Ethical approvals*

Study I and II: The study was approved by the Stellenbosch University Health Research Ethics Committee (Reference Number: N13/02/018) and was accepted by the Western Cape Department of Health (Reference Number: RP 100/2013). The identity of all participants remains confidential. All respondents gave written informed consent prior to the interviews. All transcripts had all personal details of the respondents removed. Copies of all the interviews were held only on password protected computers.

Studies III and IV: In addition to obtaining internal ethical approvals for the trial from all participating institutions prior to study initiation (The Health Research Ethics Committee of Stellenbosch University - ref N14/08/108), the trial was also registered in the Pan-African Clinical Trial Registry (PACTR201506001182385).

Access to the participants was obtained at the clinics through the Provincial Department of Health (Reference: RP 100/2013). Written informed consent was obtained from all participants prior to enrolment as required with national requirements and the principles of the Declaration of Helsinki. Confidentiality was maintained at all levels of data management. An independent data safety and monitoring inspection was performed midway through the trial. All staff who came into contact with participants completed a GCP/ethics course. Compliance with GCP was confirmed by an external clinical monitor in the first six month of the study.

## 6 POLICY IMPLICATIONS

This study suggests that messages to men in the postoperative period after VMMC should address the reality and crises the men are facing throughout the six-week period, as they are experiencing them. They must also be positive in nature and not use scare tactics to force compliance. The messages must be bite-size and simple to understand. The men constantly gave complex and compound messages a low ranking. The messages must also be culturally appropriate for the intended audience. An important aspect of message relevance was that it was linked to frequency and rate of delivery. An effective and relevant message system contained well-timed simple messages that were few in number and had a finite delivery period.

The fact that, even after careful pre-trial planning around the needs and requirements of the target audience and the clinical environment, the development of a theory-based, participant-driven m-Health programme and a rigorous and robust trial methodology, the positive effect of the intervention remained statistically non-significant, tells us that m-Health strategies cannot be used in isolation to effect behaviour-change. In this instance, it must be used in conjunction with other counselling and support programmes to safeguard men's health during this recovery period. It is essential to recognise the potential of m-Health programmes in developing countries' healthcare systems. We need to see mobile technology as a potential tool in the development of effective public health intervention programmes, especially in resource-strapped environments.

Postoperative counselling strategies must be tailor-made for the participants that they are targeting. If patients with high risk-taking personalities can be identified through the VMMC clinical uptake procedures via a brief three to five item questionnaire, these patients could then be enrolled in more intensive and sustained counselling sessions.

The study also identified the specific weeks in the recovery period that patients reported most of the sexual incidences. Weeks five and six accounted for 88% of the incidences of early penetrative sexual encounters. Targeted programmatic interventions could be designed to concentrate on this period of the VMMC patients' recovery period taking into account the pressures, which men feel to engage in penetrative sex during this time.

This study demonstrates an effective way in which to engage men in the development of their own health interventions. Rather than being passive recipients of ‘top-down’, expert-driven communications, participants in this study had the opportunity to actively participate in the message design process and engage with health information through informal interactions with experts and with one another, thereby increasing the likelihood that they adopted the recommended behaviours. Based on our findings, this methodological approach to the development of theory-driven, evidence-based and culturally appropriate health messages in mobile health interventions could be adapted to other cultural and geographic environments and various health issues. This can be used as a model to test and adapt health messages in a variety of mobile health intervention projects within a variety of cultural contexts. It can also be applied to health communication message development more generally.

Additional research is needed to determine whether this approach facilitates technology-based interventions to be an effective, sustainable way to promote healthy lifestyles to circumcised men and have a significant impact on behaviours that place men at increased risk. The overall results also raise the question of whether interventions such as these need to rather form part of a more systematic intervention rather than being seen as an individual input into the system of influences on men in this context.

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## 9 APPENDICES

**9.1 APPENDIX ONE: PARTICIPATING MMC CLINICS**

<b>No.</b>	<b>Clinic</b>	<b>Sub-Structure</b>	<b>Monthly rate</b>
1.	Bishop Lavis	Northern	Weekly
2.	Delft	Northern	Bi-monthly
3.	Elsies River	Northern	Bi-monthly
4.	Goodwood	Northern	Monthly
5.	Grassy Park	Southern/Central	Bi-monthly
6.	Green Point	Southern/Central	Monthly
7.	Hout Bay	Southern/Central	Monthly
8.	Kensington	Southern/Central	Monthly
9.	Lotus River	Southern/Central	Monthly
10.	Retreat	Southern/Central	Bi-monthly
11.	Vanguard	Southern/Central	Monthly
12.	Woodstock	Southern/Central	Weekly

## 9.2 APPENDIX TWO: VMMC PRE-SURGERY COUNSELLING PROCEDURES

There are two pre-surgery assessments done with the patient:

- A rapid VCT
- Pre-surgery procedural and post-op wound care talk

### 9.2.1 The AIDS-Test (Rapid VCT)

#### Pre-test Counselling session:

The counsellor speaks briefly to the patient on the following topics:

- What his personal history is
- Whether he has any health problems
- What his risk of being HIV infected is
- What he knows about HIV/AIDS
- Information about HIV/AIDS, including the test procedure and what people who are HIV infected can do to make sure that they stay as healthy as possible for as long as possible.
- The advantages and disadvantages for him to having the test
- What kind of support system he has including who he would be able to tell if he tested HIV positive.

#### Post Test Counselling session:

After giving him his HIV antibody results, the counsellor:

- Allows the patient to express his feeling about being HIV antibody positive, negative or indeterminate. The counsellor then helps the patient to revisit the issues he raised during the pre-test counselling session, including any plans he may have made.
- Discuss any immediate problems and help him to decide on a plan of action
- Answer any questions he may have and provide him with useful information
- Discuss positive living
- Give him positive information on what resources there are in his community to help him.

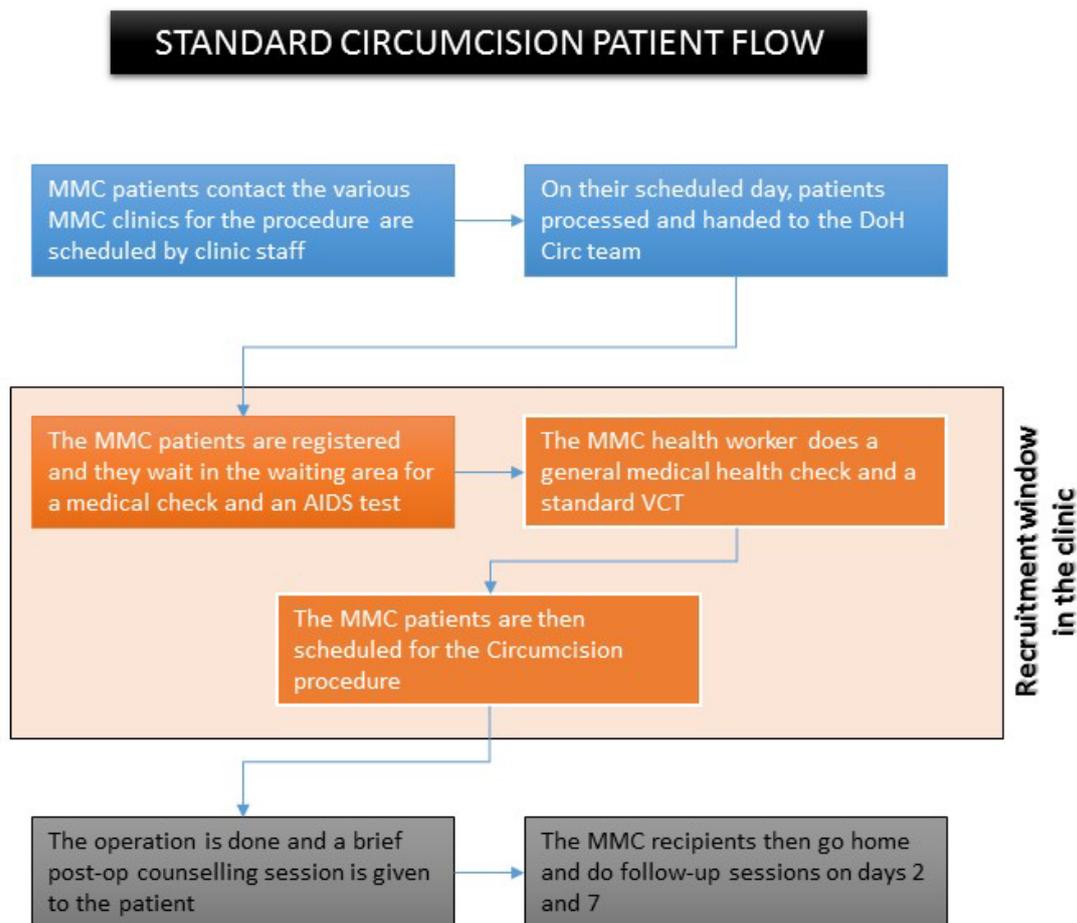
### 9.2.2 Pre-surgery procedural and post-op wound care talk

There is some procedural variance between the two circumcision teams in the two municipal sub-structures. The team in the Southern and Western sub-structures has a communal talk with the patients in the waiting room before any surgical procedure start, and the team in the Northern sub-structure does it individually with each patient just before and after the procedure. The issues that are covered are:

- What the actual procedure entail. From the initial injection to the wrapping up of the wound.
- Wound-care management:
  - The strapping of the penis against the body for the next two weeks
  - The importance of follow-up visits on days 2, 7 and 21

- The use of the saline solution to disinfect the wound
- The use of an ice bottle to combat erections
- The emphasis of the no sex/masturbation-rule for 6 weeks
- Pain management and use of medication

### 9.3 APPENDIX THREE: PATIENT FLOW WITHIN THE MMC CLINIC



## 9.4 APPENDIX FOUR: INTERVENTION MESSAGES

Day	#	Message
<b>Theme 1: Bi-daily self-care messages from day 1 to day 2</b>		
1	1	Rest! This will help with the wound healing.
	2	Get lots of rest for the next two days. It will help with the healing.
2	3	Go back to the clinic after two and seven days so the dressing can be replaced and the wound can be checked.
	4	You can take a bath a day after the surgery, but don't let the dressing get wet.
<b>Theme 2: Daily self-care messages from day 3 to day 14</b>		
3	5	Use lukewarm water to wash the wound every day. Keep the dressing dry.
4	6	Are you having a difficult time? Talk to someone you love. They will understand.
5	7	Do not pull or scratch the wound while it is healing.
6	8	If there is severe pain and the pain tablets are not helping, contact the clinic.
7	9	If you have difficulty urinating, go see the clinic.
8	10	If there is pus coming out of the wound, go to the clinic.
9	11	If there is a fever within the first week, go to the clinic.
10	12	If there is severe pain in the lower abdomen, go to the clinic.
11	13	Check for any skin tightness when you get an erection.
12	14	Want to be healthy? Look after yourself.
13	15	Bleeding that does not stop is not normal. Go back to the clinic.
14	16	Remember that circumcision does not provide 100% protection
<b>Theme 3: Daily self-care messages from day 15 to day 28</b>		
15	17	Involve your partner in the recovery period
16	18	Think about what you are going to do before you do it
17	19	Don't worry! Just a few weeks more
18	20	Just remember! Having sex before you are ready, will just set you back!
19	21	Take your time when you are pleasing your partner
20	22	Regular exercise and healthy diet are essential
21	23	You can do it!
22	24	Be proud of yourself!
23	25	Having sex too early, will just set you back!
24	26	Get rid of that painful erection by urinating frequently.
25	27	Don't be brave! Take pain tablets to relieve the pain
26	28	Did you look after your penis today?
27	29	No sex or masturbation for six weeks!
28	30	Be aware of alcohol. It impedes your judgement
<b>Theme 4: Tri-weekly self-care messages from day 29 to day 42</b>		
29	31	Make sure you listen to your partner
30	32	If you have sex before the wound is properly healed, there is a greater chance of contracting STIs or HIV
32	33	Loving is not about sex only!
34	34	You did it!
36	35	Start the day with a healthier body in mind
38	36	You don't need your penis to make love
40	37	Show restraint every day, even though it may be difficult. You will be rewarded
42	38	This procedure, with condom use, a knowledge of your HIV status and a reduction in sexual partners is the recipe for an HIV-free future.

## 9.5 APPENDIX FIVE: THE STUDY PARTICIPANTS OF STUDY I BY SEX AND RELIGION

<b>No.</b>	<b>Gender</b>	<b>Number of Participants</b>	<b>Age Range</b>	<b>Religion (Muslim; Christian)</b>
1	Male	6	19-36	4;2
2	Male	6	22-45	3;3
3	Male	6	23-63	4;2
4	Male	7	18-42	5;2
5	Male	6	20-39	4;2
6	Male	7	21-53	4;3
7	Female	4	22-41	2;2
8	Female	5	19-34	3;2
9	Female	5	25-52	3;2

## 9.6 APPENDIX SIX: INTERVIEW SCHEDULES OF STUDY I

### Interview schedule for VMMC patients

We are here to discuss a particular consideration around your decision to be circumcised. We understand that you went through adult circumcision in the last 6 months. As you may be aware, circumcision does provide protection against HIV transmission for the man. But for the immediate period, of up to 10 weeks post the operation, the man is actually at increased risk of contracting HIV, and other STDs. We are planning an intervention to try to reduce these risks, but we need to understand what would influence risky behaviour over this time. I am going to ask an initial question and there are areas of specific interest that I want to cover, but I am generally interested in what you have to say.

#### Why did you decide to get circumcised as an adult, and how was the experience?

- Reason for circumcision
- HIV / STD protection
- Expected impact on sex relationship(s)

#### Experience of circumcision

- Pain during surgery
- Pain since surgery
- Break in sex of 10 weeks
- Counselling and education received
- Complications or problems experienced

#### Importance of having regular sex

- Relationship
- Feeling like a man
- Have to please partner
- Wanting to test new version of penis

#### Satisfaction with non-penetrative sex

- Holding and cuddling
- Oral sex
- Mutual masturbation
- Inner-thigh sex

#### Changes in sexual practice

- Any changes in sexual practice since the circumcision

- Use of condoms
- Loss of sensitivity in sex
- Loss in capacity to please partners

### **Messages for intervention programme**

We are planning to use voice messages to provide educational messages on how men and couples can protect themselves until the wounds have healed.

- Content of messages
- Approach
- Timing of messages
- Information on the circumcision and healing process

### **Additional sexual partners**

- If he has more than one partner, is the negotiation of sex and safety issues the same with that partner.

### **Interview schedule for partners of VMMC patients**

We are here to discuss a particular consideration around your decision be circumcised. We understand that your primary sexual partner went through adult circumcision in the last 6 months. As you may be aware, circumcision does provide protection against HIV transmission for the man. But for the immediate period, of up to 10 weeks post the operation, the man is actually at increased risk of contracting HIV, and other STDs. We are planning an intervention to try to reduce these risks, but we need to understand what would influence risky behaviour over this time. I am going to ask an initial question and there are areas of specific interest that I want to cover, but I am generally interested in what you have to say.

### **Why did he decide to get circumcised as an adult, and how was his experience?**

- Why he decided to be circumcised
- HIV / STD protection
- Expected impact on sex relationship(s)

### **How he described the circumcision**

- Pain during surgery
- Pain since surgery
- Break in sex of 10 weeks
- Counselling and education received
- Complications or problems experienced

### **Importance of having regular sex**

- Relationship
- Partner having to feel like a man
- Have to please partner
- Wanting to test new version of penis

### **Satisfaction with non-penetrative sex**

- Holding and cuddling
- Oral sex
- Mutual masturbation
- Inner-thigh sex

### **Changes in sexual practice**

- Any changes in sexual practice since the circumcision
- Use of condoms
- Loss of sensitivity in sex
- Loss in capacity to please partners

### **Messages for intervention programme**

We are planning to use voice messages to provide educational messages on how men and couples can protect themselves until the wounds have healed.

- Content of messages
- Approach
- Timing of messages
- Information on the circumcision and healing process

### **Additional sexual partners**

- If he has more than one partner, is the negotiation of sex and safety issues the same with that partner.

## 9.7 APPENDIX SEVEN: GENERAL THEMATIC CODE LIST OF STUDY

### Reasons

1RSN\_HIV protection

1RSN\_Cleanliness

1RSN\_Religion

1RSN\_STI protection

1RSN\_Other reasons

1RSN\_External v internal LOC

1RSN\_Impact on sex

### Experience of VMMC

2EXP\_Pre-op mx

2EXP\_Op procedure

2EXP\_Pain during op

2EXP\_Pain post-op

2EXP\_Sex post-op (10 weeks)

2EXP\_Sex post-op (after 10 weeks)

2EXP\_Pre- and post-counselling

2EXP\_Post-op problems

2EXP\_Other

### Relationships

3REL\_Sex in relationships

3REL\_Being a man

3REL\_Pleasing partner

3REL\_Other partners

3REL\_Other

### Non-penetrative sex

4ALT\_Holding and cuddling

4ALT\_Oral sex

4ALT\_Masturbation

4ALT\_Thigh sex

4ALT\_Other

### Changes in sexual practices

5SEX\_Post-op changes

5SEX\_Condoms

5SEX\_Sensitivity issue

5SEX\_Capacity to please

5SEX\_Other

### Messages

6MSG\_Content

6MSG\_Approach

6MSG\_Timing

6MSG\_Healing mx

6MSG\_Cellphone

6MSG\_Methods of communication

6MSG\_Info on safety

6MSG\_Sexual information

6MSG\_Info on post-op Tx

6MSG\_Other

## 9.8 APPENDIX EIGHT: DEMOGRAPHICS AND BASELINE CHARACTERISTICS OF RCT PARTICIPANTS

Characteristics	Total	Intervention (n=579)	Control (n=579)
Age of participants (n=1194)			
<b>Age (SD)</b>	29.34 (9.38)	29.78 (9.70)	29.87 (9.04)
<b>18 - 30 yrs</b>	752 (63.0%)	367 (61.5%)	385 (64.5%)
<b>31 – 40 yrs</b>	294 (24.6%)	147 (24.6%)	147 (24.6%)
<b>41 yrs and older</b>	148 (12.4%)	83 (13.9%)	65 (10.9%)
Language (n=1173)			
<b>English</b>	604 (51.5%)	285 (48.7%)	319 (54.3%)
<b>Afrikaans</b>	517 (44.1%)	272 (46.5%)	245 (41.7%)
<b>isiXhosa</b>	38 (3.2%)	24 (4.1%)	14 (2.4%)
<b>Other</b>	14 (1.2%)	4 (0.7%)	10 (1.7%)
Education (n=1161)			
<b>Primary school or less</b>	60 (5.2%)	38 (6.5%)	22 (3.8%)
<b>High School (not completed)</b>	624 (53.7%)	319 (54.9%)	305 (52.6%)
<b>High School (completed)</b>	477 (41.1%)	224 (38.6%)	253 (43.6%)
<b>Post-matric (n=952)</b>	221 (23.2%)	112 (23.8%)	109 (22.6%)
Marital status (n=1176)			
<b>Not married and not living with a partner</b>	619 (52.6%)	296 (50.6%)	323 (54.6%)
<b>Married and not living with a partner</b>	88 (7.5%)	49 (8.4%)	39 (6.6%)
<b>Not married and living with a partner</b>	72 (6.1%)	38 (6.5%)	34 (5.8%)
<b>Married and currently living with partner</b>	223 (19.0%)	112 (19.1%)	112 (19.0%)
<b>Divorced/Widowed</b>	173 (14.7%)	90 (15.4%)	83 (14.1%)
Not living with partner (v Living with partner) (n=1176)	881 (74.9%)	436 (74.5%)	445 (75.3%)
Unemployed (v Employed) (n=1128)	573 (50.8%)	279 (50.4%)	294 (51.2%)
Religion (n=1172)			
<b>Formal Churches</b>	479(62.3%)	235(63.9%)	244(60.84%)
<b>Charismatic Churches</b>	106(13.8%)	51(13.9%)	55(13.7%)
<b>Muslim</b>	167(21.7%)	78(21.2%)	89(22.2%)
<b>Other</b>	17(2.2%)	4(1.1%)	13(3.2%)
Type of dwelling (n=1144)			
<b>Homeless or shack dweller</b>	150 (13.1%)	81 (14.2%)	69 (12.0%)
<b>Room in hostel or garage</b>	100 (8.7%)	49 (8.6%)	51 (8.9%)
<b>Flat or house</b>	894 (78.1%)	441 (77.2%)	453 (79.1%)
<b>Told you have an STI at Baseline(n=1118)</b>	196 (17.5%)	111 (19.8%)	85 (15.3%)
<b>Self-reported HIV positive status at post evaluation</b>	87 (9.70%)	43 (9.70%)	44 (9.70%)

9.9 APPENDIX NINE: TELEPHONIC FOLLOW-UP SCHEDULE

CPT\_CIRC STUDY

Version: 19062015\_03\_YT

Loss to Follow Up: Phone Survey (Form P8)



Hello,  
 My name is \_\_\_\_\_ and I am calling on behalf of a study conducted by Stellenbosch University. As you may recall, you agreed to participate in a study in the time following your circumcision and since you were unable to come to your six-week follow up appointment with us, I am calling to gather some post-operation information from you. As is with all elements of this study, your responses are confidential and completely anonymous. It is only eleven short questions and should only take a few minutes. Are you willing to participate?

No	Question	Response			
		Yes	No	Somewhat at risk	Very much at risk
1	Since your circumcision, have you been diagnosed with a sexually transmitted disease (STD)?	Not at risk	A little bit at risk	Somewhat at risk	Very much at risk
2	Based on your behavior over the past 6 weeks are circumcision, how much do you think you are at risk for getting HIV?	Rarely or none of the time (less than 1 day)	Some or a little of the time (1-2 days)	Occasionally or a moderate amount of the time (3-4 days)	Most or all of the time (5-7 days)
3	Since your circumcision, on average, how many days a week have you felt depressed?	A little of the time	Some of the time	A good part of the time	Most of the time
4	Since your circumcision have you felt more nervous and anxious than usual?	Yes	No	Refuse to Answer	
5	In the last two weeks of the recovery period (weeks 4-6) did you experience any pain or swelling of your penis?	Yes	No	Refuse to Answer	
6	Since your circumcision, has your sexual partner lived with you?	Yes	No	Refuse to Answer	
7	Since your circumcision, have you had penetrative sex (with your penis) without a condom?	Yes	No	Refuse to Answer	
8	Since your circumcision, have you had penetrative sex (with your penis) with a condom?	Yes	No	Refuse to Answer	
9	(If respondent answered yes to question 7 and/or 8 ) When was the first time you had penetrative sex following your circumcision?	Within the first three weeks after surgery	In the fourth week after surgery	In the fifth week after surgery	In the sixth week after surgery
10	Did you receive audio messages following your circumcision?	Yes	No		
11	(If respondent answered yes to question 10) How would you rate the following statement: I found this system very cumbersome to use	Strongly Disagree	Somewhat Disagree	Somewhat Agree	Strongly Agree
12	(If respondent answered yes to question 10) How would you rate the following statement: I feel very confident using this system	Strongly Disagree	Somewhat Disagree	Somewhat Agree	Strongly Agree

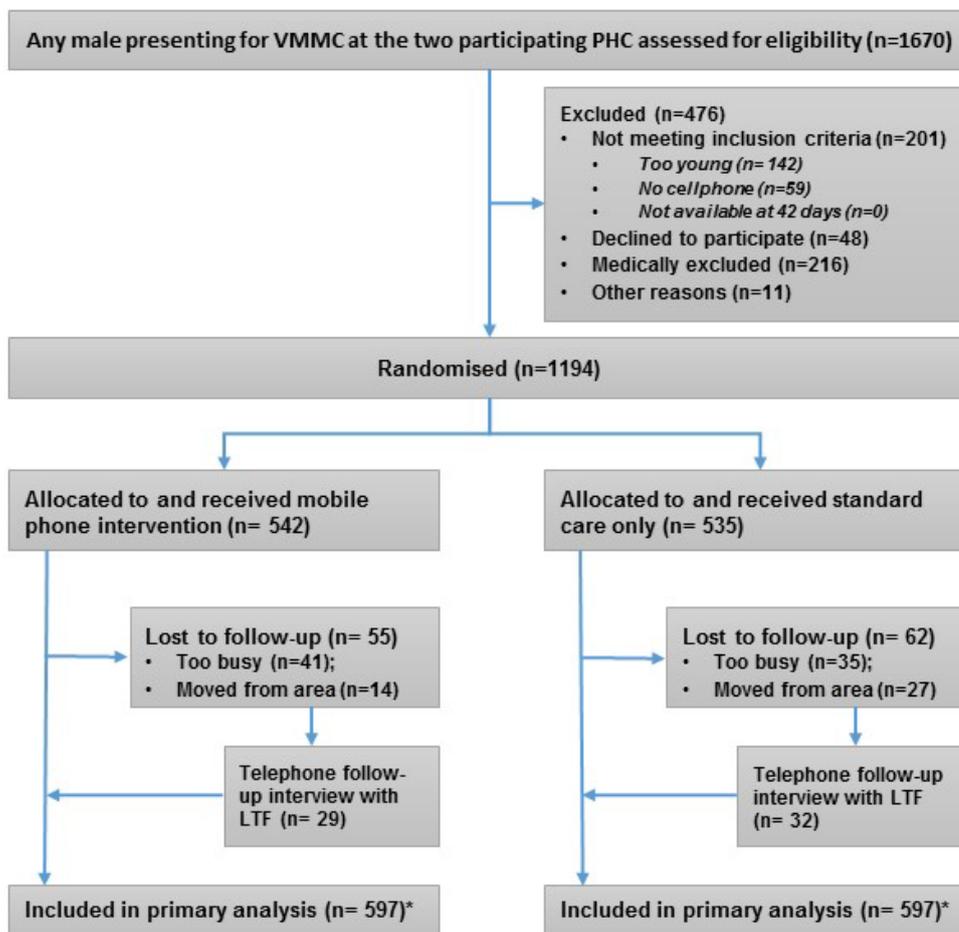
(At the completion of the survey): That is all the questions I have for you. Thank you for your time and cooperation.

Study Number:	Date completed:	Interviewer:	Captured:
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## 9.10 APPENDIX TEN: DEMOGRAPHIC DETAILS OF FOLLOWED-UP AND LOSS TO FOLLOW-UP

Variables	Levels	Completed (1138)	Loss to follow-up (56)	p-value
Age categories of participants	18 - 30	715 (62.8%)	37 (66.1%)	0.874
	31 - 40	281 (24.7%)	13 (23.2%)	
	41 and older	142 (12.5%)	6 (10.7%)	
Language spoken	Afrikaans	492 (43.3%)	25 (44.6%)	0.717
	English	575 (50.6%)	29 (51.8%)	
	isiXhosa	38 (3.3%)	0 (0.0%)	
	Other	13 (1.1%)	1 (1.8%)	
Schooling levels	Primary school or less	59 (5.3%)	1 (1.8%)	0.490*
	High School (not completed)	592 (53.6%)	32 (57.1%)	
	High School (completed)	454 (41.1%)	23 (41.1%)	
Religious affiliation	Formal Churches	462 (63.2%)	17 (44.7%)	0.021*
	Charismatic Churches	100 (13.7%)	6 (15.8%)	
	Muslim	155 (21.2%)	12 (31.6%)	
	Other	14 (1.9%)	3 (7.9%)	
Cohabiting status	Not living with partner	711 (75.2%)	36 (75.0%)	0.980
	Living with partner	235 (24.8%)	12 (25.0%)	

### 9.11 APPENDIX ELEVEN: CONSORT DIAGRAM OF THE RCT STUDY



\* Intention-to-treat design, therefore all participants were included in the analysis

## 9.12 APPENDIX TWELVE: DEMOGRAPHIC DETAILS OF PARTICIPANTS WHO AGREED TO PARTICIPATE AND THOSE WHO DID NOT

Variables	Levels	Assented to participate (1194)	Declined to participate (48)	p-value
Age categories of participants	18 - 30	752 (58.3%)	28 (63.0%)	0.430
	31 - 40	294 (22.9%)	11 (24.6%)	
	41 and older	148 (18.8%)	9 (12.4%)	
Language spoken	Afrikaans	517 (43.3%)	21 (43.6%)	0.798
	English	604 (50.6%)	26 (54.8%)	
	isiXhosa	38 (3.3%)	1 (2.1%)	
	Other	13 (1.1%)	1 (1.8%)	
Schooling levels	Primary school or less	60 (5.2%)	4 (10.0%)	0.401
	High School (not completed)	624 (53.7%)	21 (52.5%)	
	High School (completed)	477 (41.1%)	15 (37.5%)	
Religious affiliation	Formal Churches	479 (62.3%)	15 (31.3%)	0.093
	Charismatic Churches	106 (13.8%)	9 (18.8%)	
	Muslim	167 (21.7%)	19 (39.9%)	
	Other	17 (2.2%)	5 (10.4%)	
Cohabiting status	Not living with partner	747 (75.2%)	32 (72.9%)	0.674
	Living with partner	247 (24.8%)	16 (27.1%)	

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RESEARCH ARTICLE

# “What do You Mean I’ve Got to Wait for Six Weeks?!” Understanding the Sexual Behaviour of Men and Their Female Partners after Voluntary Medical Male Circumcision in the Western Cape

Yoesrie Toefy<sup>1,2\*</sup>, Donald Skinner<sup>2</sup>, Sarah C. Thomsen<sup>1</sup>

**1** Karolinska Institutet, Department of Public Health Sciences, Stockholm, Sweden, **2** Stellenbosch University, Department of Interdisciplinary Health Sciences, Tygerberg, Cape Town, South Africa

\* [ytoefy@sun.ac.za](mailto:ytoefy@sun.ac.za)



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**Data Availability Statement:** The restrictions apply to to ethical stipulations and commitments we made to the research participants that their views and opinions would be kept confidential and anonymous. Data are available from the Research on Health and Society’s secure data depository for researchers who meet the criteria for access to confidential data.” “Data are from the qualitative study whose authors may be contacted at [ytoefy@sun.ac.za](mailto:ytoefy@sun.ac.za). The restrictions apply to to ethical stipulations and commitments we made to the research participants

## Abstract

### Background

Several studies have shown that voluntary male medical circumcision (VMMC) reduces the incidence of the Type-1 human immunodeficiency virus (HIV) in heterosexual men by up to 60%. However, there is an increased risk of transmission of STIs, including HIV, in the immediate post-operative period after receiving VMMC. This study is to understand sexual practices of couples in the post-operative period in a Coloured population in the Western Cape Province of South Africa.

### Methods

Coloured Males who had undergone VMMC in the previous six months in the Cape Town area and their partners participated in eight single-gender focus group discussions. The groups explored why the men decided to undergo VMMC, what kind of counselling they received, and how they experienced the 6-week post-operative period, including sexually.

### Results

The primary motivation to VMMC uptake included religious injunction and hygiene reasons and protection against sexually transmitted infections not necessarily HIV. There was some exploration of alternative sexual practices. During the period immediately post operation the respondents spoke of pain and fear of any sexual arousal, but towards the end of the six week period, sexual desire returned. Both men and women felt that sex was important to maintain the relationship. Gaps were identified in the pre- and post-MC procedure counselling.

that their views and opinions would be kept confidential and anonymous.

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**Competing Interests:** Dr Sarah Thomsen is an Academic Editor of Plos One. This does not alter the authors' adherence to PLOS ONE policies on sharing data and materials.

## Conclusions

There is a real risk that men in this population may begin sex before complete healing has occurred. VMMC counselling to encourage men to stay sexually safe in the wound-healing period, needs to take into account the real-life factors of the circumcised men. It is essential from a public health, and gender perspective that effective counselling strategies for the VMMC post-operative period, and the longer term, are developed and tested.

## Background

### Background and context

South Africa holds the dubious title of being the country with the highest number of HIV positive individuals—over five million. [1] The Coloured community, which accounts for 48.8% of the Western Cape's population [2] has a growing HIV prevalence rate—7.6% according to the latest ante natal data. [3] The heightened HIV risk to this population group lies in a high illicit drug and alcohol use in the community, which is associated with risky sexual behaviour [4–6].

Due to its known protective effects [7–9], the South African Department of Health has made a commitment to rolling out voluntary medical male circumcision (VMMC) in all provinces [10–11]. Thus far, about 3,600 medical circumcisions have been performed at the government's Male Circumcision clinics since the start of the provincial VMMC rollout at the end of 2010 until April 2013 in the province. The Xhosa community, who make up 21% of the population in the province, practice traditional circumcision as part of the initiation of boys into adulthood and therefore consider medical circumcision outside their cultural norms [12]. There is little knowledge about the perceptions of VMMC among the Coloured population in the Western Cape. What is known is that the Coloured community do not consider HIV as a disease that affects their community [6, 13–14]

Sexual contact carries an increased risk of transmission of STIs, including HIV, in the immediate post-operative period after receiving VMMC. However, it appears that resumption of sex after the VMMC procedure is not unusual. In an observational study in Nyanza, Kenya, 30.7% of all participants and 65.7% of married or co-habiting participants, resumed sexual intercourse before wound healing, usually in the first 3–4 weeks after VMMC, despite counselling [15]. In the study conducted in Kisumu, Kenya, they also found the risk factors for sex before healing were being married or having 2 or more sex partners in the last year [16]. Similarly, in Zambia, 24% of men reported resuming sex early, 46% of which did so in the first three weeks [17]. In the Rakai, Uganda VMMC trial, about 11% of HIV+ and HIV- participants reported having intercourse before certified wound healing, despite intensive pre- and post VMMC counselling and despite the men knowing their HIV status via the HIV test they received as part of their Standard of Care package. Female partners of HIV infected trial participants were 3.5 times *more* likely to acquire HIV if the couple resumed sexual intercourse early than the partners of those who did not receive VMMC (the control group), causing the authors to conclude that “. . . strict adherence to sexual abstinence during wound healing and consistent condom use thereafter must be strongly promoted when HIV-infected men receive circumcision.” Ironically, the risks of sero-conversion to HIV due to early resumption of sex after MMC seem to be especially high for women in the short term [18]. In fact, Hewett et al found that the model estimates that of the 61 000 men circumcised in one year, early resumption of sex leads to 69 extra HIV infections (32 among men, 37 among women), but estimates a net effect of 230

fewer HIV infections in one year, predominantly among men. 16], Recommendations have been made for developing and evaluating optimal counselling strategies among men seeking VMMC and to assess the effectiveness of behaviour change communication strategies [19]. One intervention, consisting of a 3-hour behavioural change component, has shown to be effective in preventing risk compensation behaviour three months after VMMC [20]. However, to our knowledge there is little scientific data about what works in the immediate post-operative period. In addition, there is a recognition that lack of human resources presents a barrier to the provision of such intense services, particularly if repeated messaging is to occur. Clearly, more innovative strategies for communicating with, and effectively altering behaviour in, men and their partners in the post-operative period of VMMC are needed in South Africa. As part of this development more knowledge is needed about current users of VMMC in order to find the best messages to include in these innovative strategies.

The primary objective of this study was to seek some understanding on why men in a predominantly Coloured community of South Africa, sought VMMC and to document their experience of the post-operative period in terms of penile recovery. Additionally, we wanted to understand the reasons why men might resume sex early after the VMMC procedure. Finally, we also wished to explore strategies that couples employ to negotiate the 6-week recovery period. The aim was to influence the counselling strategies of the VMMC programmes in this area in order to promote healthier sexual behaviour after the VMMC procedure. The term 'healthier sexual behaviour' is meant to cover both abstinence and non-penetrative sex.

## Methodology

A qualitative approach using focus groups discussions was used to develop a better understanding of how men and their partners feel about VMMC and sexual patterns around this time period.

**Setting.** The research was done in catchment areas of the Heidevelt Public Health Clinic and Mitchells Plain Hospital in Cape Town, in the Western Cape Province of South Africa. The study sites were chosen in conjunction with the provincial health department. The communities in the catchment area of the two selected township areas are almost exclusively Coloured, Afrikaans-speaking. The term Coloured refers to an official South African race group that is predominantly mixed ancestry that is used in research and census data. There is a large Muslim population (10–15%) in the catchment area for one of the townships. Both areas are densely populated with a low socio-economic base. The housing is typically one to two-bedroom "maisonette" housing with an average population density of 9,600 per km<sup>2</sup>. In 2011, the population of the suburb Mitchells Plain was 310 485 and the average household size was 4.57 [2].

The two healthcare institutions from which the sample was drawn have been offering VMMC as a form of protection from HIV for men since 2011. The clinics operate one morning a week on an appointment-only basis.

**VMMC counselling procedures.** On the day of the operation, the patient is asked to come in early for a mandatory HIV test including pre- and post-test counselling. If the patient tests positive, then the circumcision procedure is deferred until he can produce a CD4 count above the ARV admission point. The surgical procedure follows a strict protocol developed by the South African National Department of Health with the assistance of the Medical Male Circumcision task team including, South African National AIDS Council, UNAIDS, World Health Organization and others. [21] A very brief post-operative counselling session is conducted with the patient before he is discharged with information on how to care for the wound, on

**Table 1. The study participants of the focus groups by sex and religion.**

No.	Gender	Number of Participants	Age Range	Religion (Muslim; Christian)
1	Male	6	19–36	4;2
2	Male	6	22–45	3;3
3	Male	6	23–63	4;2
4	Male	7	18–42	5;2
5	Male	6	20–39	4;2
6	Male	7	21–53	4;3
7	Female	4	22–41	2;2
8	Female	5	19–34	3;2
9	Female	5	25–52	3;2

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avoiding penetrative sex during the six week recovery period, and on the necessity for condom use for safe sex after wound healing.

**Sample.** The study included six focus groups with men and three with women (Table 1). The sampling was done in conjunction with the booking officers at the two clinics. Male participants were drawn from their theatre records of the last six months. The records consist of monthly lists of names, ages and contact details of VMMC recipients over the past six months. The fieldworker contacted all men on the clinic lists starting from the earliest month to the latest. Three men refused to participate at the initial contact point, claiming time-constraints, and five men who initially agreed to participate, did not arrive at the group sessions. No information is available on them and other than citing time constraints, no other reason for not coming were given.

At the end of each focus group, the facilitator asked the participants the names and contact details of their sexual partners over the six-week post-operative period. Of the 38 men who participated, 26 men gave details of their partners. Reasons for not giving the details of their partners ranged from not knowing where their ex-partners are to the stated conviction that their partners would not participate in focus groups. No men reported having a male partner. The researcher contacted these partners and ended up with three focus groups with women who were partners of men who had recently undergone VMMC. Seven women refused to participate (time constraints, personal reasons) and five women did not arrive at the sessions. No additional information is available on those who did not participate.

All of the participants had been residents in the community for most of their lives and were Coloured. The population of the clinic’s catchment area is largely of the ‘Coloured’ race group and also 10–15% Muslim.

**Interview schedules.** The interviews covered issues around the reasons why they chose to be medically circumcised as adults, what the experience of the actual procedure entailed, and how they coped with any discomfort or pain during the initial recovery period. The interview then delved into the coping mechanisms employed later in the six-week period, particularly around the issues of desire and sex. The interview attempted to investigate the cultural importance of maintaining a sexual relationship with a regular partner.

The interviewer, who is first author, is skilled in doing qualitative interviews and was key in developing the research instruments. He is a resident of Cape Town who has done other research projects in similar communities. This was felt to be important as fairly sensitive topics were allowed to be explored fully by the participants.

All interviews were conducted in Afrikaans, tape recorded and then transcribed and translated into English.

**Analysis.** A contextualized content analysis approach was used to analyse the data [22]. All the interviews were read several times by the authors so that a familiarity with the material could be established. On the basis of this familiarity, a set of themes were drawn out revolving around reasons for seeking VMMC, the experience around the procedure, the impact (short and long-term) of the procedure on relationships and sexual behaviours. The first author used these themes to code the interviews with the assistance of Atlas.ti. The themes formed the basis for the analysis presented below. Once the provisional analysis had been done all the interviews were reread, as a validity measure, to check for contradictory findings, and if any information had been inadvertently excluded. In the analysis we acknowledge that using a male interviewer could have impacted the validity of the responses of the female participants. We have taken this into account in the analysis.

**Ethics.** The study was approved by the Stellenbosch University Health Research Ethics Committee (Reference Number: N13/02/018) and was accepted by the Western Cape Department of Health (Reference Number: RP 100/2013). The identity of all participants remains confidential. All respondents gave written informed consent prior to the interviews. All transcripts have had all personal details of the respondents removed. Copies of all the interviews are held only on password protected computers.

## Results

Although the subject matter was culturally sensitive and potentially emotive, the male participants were surprisingly candid and open to the questions asked. The female participants were much more inhibited, possibly because the facilitator was a male.

### Reasons for seeking VMMC

All the Muslim men who underwent VMMC did so as a precondition for converting to Islam and the majority did so to marry Muslim women. There is a strong religious and cultural directive to circumcise Muslim male infants in the first three weeks following birth. This directive extends to men entering Islam as adults. So for many the decision was due to external family pressure and not a decision taken to protect themselves or their partners. They may not even have been aware of the protection component before they requested the service. In these cases their partners may not have even been involved in the decision making as it is a prescribed duty to convert (and be circumcised) if the men were to marry a Muslim woman.

*“... so I agreed to convert to Islam and her father insisted that I get a “soennat” [A Malay culture word meaning circumcision].” (Male, Muslim, 23 years)*

*“... [but] I would have never considered doing it if I didn't have to convert to Islam.” (Male, Muslim, 20 years)*

All of the Christian participants cited cleanliness as a reason for seeking VMMC. The explanations centred on the presence of dirt or leftover material such as sweat or semen, the bad smell and the additional need for cleaning. This was found to be repulsive to both parties, but especially to the female partners (including Muslim females).

*“It's true about the smell. I have always been aware of my smell and no matter how many times I washed and cleaned behind the foreskin that smell would always be in my nose.” (Male, Christian, 27 years)*

*“You know, all that dirt that sits under the skin. It’s not nice. . .” (Female, Muslim, 19 years)*

None of the participants gave HIV as a reason for seeking VMMC. Comments in the groups indicated that they felt safe from HIV, that it belonged to other areas of the country or to other racial communities. The Coloured community has historically had a lower level of HIV infection, and do not see themselves as vulnerable. There is a strong undercurrent of racism and stigma in the community as HIV is seen as a ‘Black’ disease or a disease that belongs to other distant communities. As indicated earlier, however, this prevalence level is changing [3].

*“In my case, not really. It’s just that those things are not really in mind, you know. It’s nice to know that it does. . .” (Male, Christian, 51 years)*

*“It’s not important to us here in Cape Town, perhaps there in KwaZulu-Natal. . .” (Female, Christian, 34 years)*

Some participants gave health reasons for undergoing the procedure. While not relating to HIV specifically, the connections were made to other sexually transmitted infections (STIs). This arose from both the male and female respondents.

*“Well, in my case, it was a factor because of my past history with STIs.” (Male, Christian, 42 years)*

*“I’m actually the reason why my husband went for the operation. . . My bladder has always an infection in it.” (Female, Muslim, 29 years)*

Besides religious influences and partners pushing them, pressure also came from their doctors or clinic nurses when they presented with STI-related symptoms.

*“. . . and I was actually forced by my doctor to do it because for as long as I can remember, I have been having problems down there.” (Male, Christian, 47 years)*

## Issues arising in the post-operative period

Participants reported on the issues arising in the post-operative period as being different depending on how much time had elapsed. Therefore, we present the results here in different periods: 1) the first two weeks, 2) weeks 3–4, and 3) weeks 4–6.

A few participants spoke about the pain or discomfort during the operation and until the aesthetic wore off, although most seemed surprised at the simplicity of the procedure.

*“The actual op wasn’t that sore. It was quick” (Male, Muslim, 31 years)*

Discussions about the first two weeks were primarily centred on recuperation and health-related issues. Respondents spoke particularly about how painful this period was. The respondents found this time period very difficult to cope with and struggled to deal with the discomfort and pain. It was treated with some humour during the discussion, but at the time they clearly struggled. There was no consideration of sex and arousal caused an escalation in pain.

*"I'm not going to lie. It was bloody sore. When the medicine wore off, it was paining like hell."*  
(Male, Muslim, 18 years)

*"(laughs) He was like a baby for more than two weeks, shame. . ."* (Female, Christian, 43 years)

The next two weeks (weeks 3 and 4) revolved around coming to terms with the change in the look and feel of the penis, discomfort in doing ordinary things, and the initiation of sexual feelings. Over this time there was beginning of a return to normal especially as the pain and discomfort reduced. The soreness was still there, however, and so any arousal was still painful. Respondents developed their own ways of trying to deal with the pain and prevent themselves getting aroused.

*"At first, I didn't like the way my penis looked, all bloated and red. Only after a few weeks, it started looking okay."* (Male, Muslim, 34 years)

*He used to keep a cold tin of Coke in the fridge and in the morning he would be sore and then he would keep the tin down there to get it down (laughs)."* (Female, Muslim, 30 years)

Participants generally reported no sexual activity in the first three weeks with some painful erections towards week three. Some reported masturbatory activities and oral sex from week four and there were a few who reported incidences of penetrative sex at weeks five and six. Although the penis remained very sore, they were able to have some form of sexual contact. When prompted, none of the participants mentioned condom use during this period.

*"No she did it with her hand and she was careful with the wound. . ."* (Male, Muslim, 27 years)

*"I know I shouldn't have done it, but we came from a party and we both had way too much to drink, and it just happened, you know. . .it was bloody sore afterwards and I tore the scabs a bit, but it was okay afterwards."* (Male, Christian, 35 years)

Participants who developed complications such as infection, swelling or wound tearing were generally happy with the post-operative staff and after the procedures in place. These complications were all reported in the first three weeks following surgery. Standard procedures are in place in the clinics for the VMMC men to return after three and seven days so the clinic staff could check the wound. All participants reported that they were told to go to the clinic in case of complications and all who reported a medical complication reported that they went back to the clinic.

*"I had an infection around the wound in the first week, but the clinic sorted me out nicely."*  
(Male, Muslim, 22 years)

## Non-penetrative sexual behaviour

In order to explore potential post-operative counselling topics, we asked participants about how they dealt with the recommended abstinence period when sexual desire returned and penile pain faded. During weeks four to six, participants reported engaging in some

non-penetrative sexual behaviour such as kissing, fondling, finger penetration and oral sex. There was an interesting distinction between how men and women viewed these behaviours. Men generally viewed them as poor substitutes to 'real sex' and they expressed relief when they were allowed to engage in penetrative sex after the wound-healing period. Women, on the other hand, expressed gratification with non-penetrative sex where the emphasis was no longer on penile penetration. The "non-penetration-rule" almost forced the male to consider their partner as a sexual being with multiple erogenous areas other than only her vagina. It cultivated a greater awareness between the partners which was positively identified by the female partners.

*"Just because you're not having penetrative sex does not mean you are not having sex."  
(Female, Christian, 28 years)*

*"Things just got hot and I had to use my fingers and my mouth to satisfy her. It was difficult. . . ." (Male, Muslim, 21 years)*

*We were much more aware of ourselves, you know? Rather than concentrating on getting it on, we got to know one another more. . . learnt other parts of our bodies were also there. . ."  
Christian female, 32 years)*

### Changes in penile sensitivity

Many participants reported a change in the physical act of sex. One spoke about the perception that exists in the community that circumcision is linked to loss of sexual capacity. Both men and women reported the men having lower sensitivity and taking longer to achieve orgasm. This was felt to be both positive and negative. Some felt that the decrease in penile sensitivity helped men with premature ejaculation difficulties, but it also aggravated erectile dysfunction problems in others. Women reported having to work harder in maintain their partners' erection. This heightened the insecurities around their own sexual identity

*". . . told me that he heard from a friend . . . that circumcision actually takes all the feeling away down there and that this person actually couldn't get it up anymore. Naturally I was worried about that. . ." (Male, Muslim, 19 years)*

*"It was okay, it wasn't as nice as before, but I guess you get used to it. . ." (Male, Muslim, 18 years)*

*"He took a lot longer to be excited, you know, get ready" (Female, Muslim, 42 years)*

*". . . much better now, I can control it better." (Male, Christian, 21 years)*

*"He looks much cleaner and it lasts much longer. . ." (Female, Christian, 34 years)*

The issue of wearing condoms, however, did not change. When prompted, very few participants reported regular condom use, even those who professed to risky sexual behaviours such as casual and multiple partners.

*"(laughs) Condoms? Why?" (Male, Muslim, 21 years)*

*I know it [condoms] protects and all that, but we are not sleeping around, so we don't need it. . .* (Female, Muslim, 29 years)

## Sex in the relationship

Difficulty in abstaining in the post-operative period has been identified as reason for early resumption of sex [15]. Therefore, in this study we also explored how important sex was for couples. We found that the sexual act plays a very important role in the participants' relationships. It speaks to gender identity, desire, fear of partners being unfaithful and the projection of sexual needs on to partners. To the men, virility is linked to manhood so the need to keep women from being unfaithful feels a bit like wanting to maintain their property. Women also emphasised the role of sex in their relationships, albeit linked to partnership security and keeping the partner sexually satisfied. Both genders reported a need to use sex to maintain the relationship and keep their partner happy and interested.

*"If you don't satisfy her, you can be sure that one day she is going to look somewhere else."* (Male, Christian, 39 years)

*"Men (laughs.) We have to keep them happy. . ."* (Female, Muslim, 47 years)

*"You can never be in a relationship without having sex."* (Male, Christian, 52 years)

*"Yes, sex and love work together."* (Female, Muslim, 25 years)

A majority of our participants' comments indicated that men and women believe that they are very different sexual beings. A message that recurred throughout our focus group discussions was that men are more sexually driven than women, and that women have an innately lower libido than men. The purpose of sex was also perceived to be different for men and women. Men spoke more about the raw physical drives of sex, with some mentioning that self-gratification is sought almost at the expense of the partner. Women referred to the sexual act as a component of a relationship.

*"It's that male/female thing. For men I think it is just . . . well, it's physical. It's like they build up that sperm and they need a release"* (Female, Muslim, 22 years)

*"I guess for men, if you could satisfy yourself, you don't care about the girl."* (Male, Christian, 31 years)

*"I always felt like my husband was more of a sexual person than I was, but I always thought that was because men were more hot-blooded and wanted instant pleasure more than women."* (Female, Muslim, 52 years)

Finally, the comment cited in the title—"What do you mean I've got to wait six weeks?!"—was made by one of the participants during an informal chat at the end of a session (outside of the focus group setting), referring to his reaction when the health worker informed him about the no-sex restrictions during the wound-healing period.

## Discussion

In this study we sought to understand the experiences of the post-operative period after receiving VMMC of men and their female partners, from a primarily Coloured population. Participants in this study reported their primary motivation for seeking VMMC as being religious injunctions or for health benefits. Those men who were to convert to Islam as adults had decided to undergo the procedure within the first year after conversion. Islam as well as Judaism, stresses the hygienic benefits of circumcision as the main reason for its emphasis, although this was not voiced by the participants.

The issue of free choice is a dominant theme in the groups. It appears that very few of the Muslim men who came for VMMC did it by personal choice. They came because of religious requirements, partners need or health service insistence. This lack of choice might influence the male's sexual behaviour over the six weeks as well as his willingness to adhere to rules including the non-penetration rule.

Among the non-Muslim participants a dominant reason for undertaking the procedure was hygiene. Both men and women named the presence and smell of dirt and semen trapped under the foreskin as motivation. Cleanliness is often seen as being the opposite of diseased [23], so it might not be seen as a specific attempt to reduce STIs, but there may have been a subliminal link to becoming disease-free.

VMMC is seen as an important tool in the HIV prevention toolkit. In a study conducted in 2012 in urban Swaziland the authors found that male circumcision, in general, is likely to foster protective behaviour change such as more responsible attitudes towards safe sex, reducing sexual temptation and partners and easier condom use [24]. Although none of the participants in the present study cited HIV prevention as a reason for undergoing the procedure, our analysis found a number of men were encouraged to seek circumcision due to their high exposure to STIs. Although many participants knew that circumcision would provide some protection against HIV, there was a sense in the groups that this was not enough reason to get circumcised. With a rising HIV prevalence in the Coloured population, and the study participants' stated aversion to condom use [25], there remains a heightened risk to HIV and other STIs. Racial communities in South Africa are still separated from each other in many ways, particularly in sexual relationships. The phenomenon of ascribing the HIV epidemic as a disease of 'other race groups' serves to perpetuate undue risky behaviour and stigma towards other groups. Thus, it may be that participants were unwilling to cite HIV prevention as a reason for male circumcision, even if this was a motivator. The alternative, that they really do not see themselves at risk of HIV, is more worrying, given the generalized nature of the epidemic in the Coloured population.

We also sought to address the phenomenon that has been reported in other settings [24] that men, especially men in committed relationships, engage in penetrative sex before the recommended wound-healing period of six weeks has been completed. We indeed found that after 4–5 weeks of no 'real' sex, tensions arose due to several factors. As described above, couples live in fairly densely populated areas in small and cramped houses. Living in very close quarters with each other with very little interpersonal space, makes it difficult to avoid sexual arousal and the need for sexual gratification. The real drive for sexual contact is obviously very high. Additionally, men felt pressure from the socially-induced fear of failing to satisfy their partners and therefore not maintaining the harmony of the relationship. These factors lend a powerful motivation to forgo the 'no penetration'-rule. Thus, some men did report penetrative sex during this period. All reported instances of penetrative sex were either fuelled by alcohol or an escalation of non-penetrative sessions, where the normal sexual patterns between the two partners overrode the 'temporary' restrictions placed on them by the procedure.

We also wanted to gain a better understanding of the interpersonal and cultural constructions of gender identity and how they relate to sex and sexuality. Such knowledge could potentially aid in developing more appropriate VMMC counselling interventions. Thus, we looked at the perceptions of men and their partners on having to withdraw from penetrative sex in the post-operative period on the men and their partners and on their relationships and the forms of non-penetrative sex practised and other ways of stabilising the relationship. Fundamental to this was how men and women perceived the role of sex in relationships.

Although the departure points are different for both genders, the importance of sex in the relationship was highlighted by both. This difference speaks directly to issues of gender identity. Whereas the males saw sex as a physical act that confirmed masculinity, many males saw the intimacy as a mechanism to maintain the relationship. The role as the provider, whether it was sustenance, physical items or intimacy, was paramount to men's understanding of what it means to be a man. Women, on the other hand, saw sex more as an affirmation of a relationship and their role to provide a home for the 'basal' needs of the man.

The discussions indicated that both men and women in this population saw sex as essential to a good relationship and that men are perceived to be more sexual than women. Moreover, men commonly experienced conflict around sex and used emotions to manage their own and their partners' feelings about sex. A general theme around sex that emerged in the analysis was that men and women view sexual activity as a gauge of marital success.

The importance that couples place on sex in relationships means that it is essential to understand how couples negotiate the six-week abstinence period, particularly the last two weeks. The participants of this study said they engaged in non-penetrative sexual activity, such as rubbing, mutual masturbation, kissing or cuddling that they employed during this period. Some even included penetrative aspects such as with a finger or the mouth in oral sex. The participants reported using some of these methods as alternatives to penile penetrative sex. There was a general feeling among male participants, however, that it was a poor substitute for 'real sex'.

We also asked about issues related to penile function after VMMC as it was linked to erectile dysfunction. The sensitivity of the cut penis had both negative and positive comments. Negative, because it was not as responsive or pleasurable as before and that influenced erectile duration and quality especially in the older men. It was also positive because circumcised men took longer to reach ejaculation, which was viewed as an advantage by both genders, rather than a complication. These issues would benefit from further explanatory research.

## Implications for public health practice

The results of this study have relevance for guiding the design of VMMC services in the Cape Town area. Findings could be of relevance for the recruitment of Coloured populations to VMMC, which is an important tool in the health department's HIV prevention toolbox. The Coloured population does not seem to be motivated to undergo VMMC for HIV prevention reasons. On the other hand "STI prevention" and "hygiene" seem to be acceptable motivators. Thus, recruitment campaigns for VMMC in this province may be more successful if it is not promoted as "HIV prevention."

Our results also point to potential topics to be included in pre- or post-operative counselling for VMMC patients. First, given the centrality of sexually conjugal relations in the population accessing the services, and the frustrations expressed with the post-operative abstinence period, it seems advisable to discuss this topic with the patient. One possibility is helping the patient to develop a plan for how he (and his partner) will negotiate the recommended abstinence period. Alternatives to penetrative sex should be discussed. Avoidance of alcohol and drugs, which may induce sexual arousal, during this period should also be discussed.

Finally, the number of participants who did not think that condom use was important is worrisome. The necessity of condom use to avoid transmission of STIs between partners should be stressed in counselling. This is, of course, particularly important for those patients who are found to be HIV positive or who are referred because of frequent STIs.

The effectiveness of counselling in behavioural change is varied. VMMC services are relatively new and often carried out in settings with limited human resources. Long counselling sessions are often not realistic. In some areas of South Africa, such services are being carried out by independent actors holding “vaccination camps.” It is essential from a public health, and gender, perspective that effective counselling strategies for the VMMC post-operative period, and the longer term, are developed and tested.

### Limitations of study

The study has several potential limitations. Firstly, we recorded the responses of only a small number of participants in a somewhat artificial environment. We cannot rule out the possibility that participants may have felt pressured to respond in certain socially acceptable ways. We tried to minimise this by stressing confidentiality, and that their fellow participants went through the same experiences. Secondly, the female groups were facilitated by a male facilitator. Although the facilitator is very experienced and went out of his way to create a safe environment, this may have hampered spontaneous discussion on fairly sensitive topics. For example, female respondents may not have felt comfortable describing sexual frustration during the recommended abstinence period to a male interviewer, and thus resorted to explanations that are more firmly rooted in socially acceptable norms. Thirdly, for logistical reasons, the focus groups were held in the month of Ramadan, which also potentially hampered candid discussions on sex and relationships for the Muslim participants. Fourthly, data on HIV status and/or having a long-term versus casual partner, which may affect perceptions of MMC or sexual behaviour in the post-operative period, was not collected. Such information could have added additional depth to the analyses. Finally, we do not know to what degree the sample we recruited was representative, but it is likely that the high representation of Muslims is a reflection of the population seeking VMMC services in the area.

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### Author Contributions

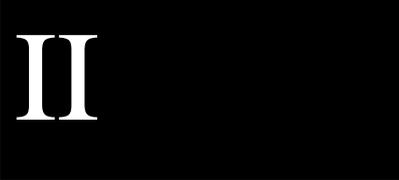
Conceived and designed the experiments: YT DS ST. Performed the experiments: YT DS ST. Analyzed the data: YT DS ST. Contributed reagents/materials/analysis tools: YT DS ST. Wrote the paper: YT DS ST. Conducted the fieldwork: YT.

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II



Original Paper

# “Please Don’t Send Us Spam!” A Participative, Theory-Based Methodology for Developing an mHealth Intervention

Yoesrie Toefy<sup>1,2\*</sup>, MBc ClinEpi, MA (Research Psych); Donald Skinner<sup>1\*</sup>, MPH, MA Clinical Psychology, PhD Psych; Sarah Thomsen<sup>2\*</sup>, MPH, PhD

<sup>1</sup>Research on Community and Health, Department of Community Health Sciences, Faculty of Medicine, Stellenbosch University, Cape Town, South Africa

<sup>2</sup>Karolinska Institutet, Department of Global Health, Karolinska Institutet, Stockholm, Sweden

\*all authors contributed equally

**Corresponding Author:**

Yoesrie Toefy, MBc ClinEpi, MA (Research Psych)  
Research on Community and Health  
Department of Community Health Sciences, Faculty of Medicine  
Stellenbosch University  
Suite 4009, Teaching Block, Tygerberg Campus  
Franscie van Zyl Drive  
Cape Town, 8000  
South Africa  
Phone: 27 784510221  
Fax: 27 219389624  
Email: [ytoefy@sun.ac.za](mailto:ytoefy@sun.ac.za)

## Abstract

**Background:** Mobile health solutions have the potential of reducing burdens on health systems and empowering patients with important information. However, there is a lack of theory-based mHealth interventions.

**Objective:** The purpose of our study was to develop a participative, theory-based, mobile phone, audio messaging intervention attractive to recently circumcised men at voluntary medical male circumcision (VMMC) clinics in the Cape Town area in South Africa. We aimed to shift some of the tasks related to postoperative counselling on wound management and goal setting on safe sex. We place an emphasis on describing the full method of message generation to allow for replication.

**Methods:** We developed an mHealth intervention using a staggered qualitative methodology: (1) focus group discussions with 52 recently circumcised men and their partners to develop initial voice messages they felt were relevant and appropriate, (2) thematic analysis and expert consultation to select the final messages for pilot testing, and (3) cognitive interviews with 12 recent VMMC patients to judge message comprehension and rank the messages. Message content and phrasing were guided by the theory of planned behavior and the health action process approach.

**Results:** Patients and their partners came up with 245 messages they thought would help men during the wound-healing period. Thematic analysis revealed 42 different themes. Expert review and cognitive interviews with more patients resulted in 42 messages with a clear division in terms of needs and expectations between the initial wound-healing recovery phase (weeks 1–3) and the adjustment phase (weeks 4–6). Discussions with patients also revealed potential barriers to voice messaging, such as lack of technical knowledge of mobile phones and concerns about the invasive nature of the intervention. Patients’ own suggested messages confirmed Ajzen’s theory of planned behavior that if a health promotion intervention can build trust and be relevant to the recipient’s needs in the first contacts, then the same recipients will perceive subsequent motivational messages more favorably. The health action process approach was also a useful tool for guiding the phrasing of the messages. Participants were more positive and salutogenic than public health experts.

**Conclusions:** The system showed how a process of consultation can work with a set of potential recipients of an mHealth service to ensure that their needs are included. Classic behavioral theories can and should be used to design modern mHealth interventions. We also believe that patients are the best source of messaging, ensuring that messages are culturally relevant and interesting to the recipient.

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**KEYWORDS**

mHealth; male circumcision; postoperative wound-healing period; health promotion; audio messaging; behaviour change

**Introduction**

Voluntary medical male circumcision (VMMC) has been shown to reduce the risk of male acquisition of human immunodeficiency virus (HIV) by as much as 60% [1-3]. This led the World Health Organization/Joint United Nations Programme on HIV and AIDS to endorse that male circumcision should be promoted as an additional strategy in the prevention of HIV in men [4] and subsequently to plan for scale-up of VMMC services in 13 countries in Eastern and Southern Africa with high HIV prevalence and low rates of male circumcision, including South Africa [5]. However, there have been concerns about the quality of health education provided to men who are circumcised, particularly in relation to “risk compensation,” early resumption of sex, and the potential risk to their female partners [6]. Early resumption of sex, defined as having sex before the wound has healed, usually around 6 weeks, is a particular risk of widespread rollout of VMMC. Although challenges persist, including inadequate counselling, education, and follow-up, especially for married, discordant couples [7,8], very few programs have addressed early resumption of sex. VMMC counselling to encourage men to stay sexually safe needs to be maintained throughout this wound-healing period and to take into account the real-life risk factors of the circumcised men. Many overburdened public health systems are unable to provide adequate intervention programs to assist these recently circumcised men.

Recommendations have been made for developing and evaluating optimal counselling strategies among men seeking VMMC and to assess the effectiveness of behavior change communication strategies [9]. However, lack of human resources in the VMMC scale-up countries presents a barrier to the provision of such intense services, particularly if repeated contacts and encouragement are to occur. Moving programs to the realm of self-care would alleviate this burden and provide patients with high-quality care. Evidence from Southern and Eastern Africa indicates that some men, particularly those who are married or cohabiting, initiate sexual intercourse before the wound has completely healed. Identifying culturally acceptable and effective interventions is imperative to ensure that scale-up of VMMC in Eastern and Southern Africa is not accompanied by additional sexual morbidity and mortality. Furthermore, given the human resource shortages accompanying the rollout of VMMC in Eastern and Southern Africa, innovative strategies are needed for delivering these interventions. This is particularly the case when countries turn to independent partners to carry out mass, one-off VMMC campaigns outside of the normal constellation of services [10]. Clearly, more innovative strategies for communicating with, and effectively altering behavior in, men and their partners are needed. Further, given evidence of greater risk for early resumption of sexual activity in married or cohabiting men, strategies for navigating the postoperative period through, for example, nonpenetrative sexual activity should be developed and included in such education.

Self-care programs within the public health sector have been considered as a viable stopgap measure to address the service delivery challenges within the sector. Chronic staff shortages and budgetary constraints are common features of public health systems of most developing countries [11]. Due to these challenges, mHealth—the use of mobile phone technology to deliver health care—has emerged as an important and appreciated complement to health care education delivered through traditional channels [12]. Such technology may include the use of text messaging, video messaging, voice calling, and Internet connectivity. The potential for mHealth interventions to partially compensate for physical clinics in resource-poor areas is enormous [13].

Mobile health solutions have the potential of reducing burdens on health systems and empowering patients with important information. However, theory-based mHealth interventions are lacking, despite the fact that some theories of behavior change are well validated and tested on evidence-based interventions of prevention, diagnoses, and care [14-16]. Instead, all too often, mHealth interventions rely on the novelty of their modus operandi, as opposed to behavior change theory.

**South African Context**

South Africa holds the dubious title of being the country with the highest number of HIV-positive individuals—over 5 million [17]. Based on the 2010 antenatal data, it was estimated that 18.5% of women in the Western Cape presenting at antenatal services were HIV-positive, with an incidence estimate of 6.2% [18]. The national prevalence based on these data was 30.2%. Transmission of HIV in South Africa is almost exclusively through heterosexual sex, thus heightening the importance of circumcision as a form of prevention. The South African Department of Health has made a commitment to rolling out medical circumcision in all provinces as one source of protection from HIV [4]. Approximately 5 million adult men could potentially be targeted. Circumcision is provided as part of a comprehensive service at district hospitals and includes HIV testing, counselling, and HIV education before the procedure.

Mobile phone use and access in South Africa is virtually universal. Mobile phone technology has been found to be acceptable and feasible for HIV- and AIDS-related prevention and services [19], and is now used in several health-related text-reminder projects in South Africa [20].

**Theoretical Frameworks Considered for the Development of Our Intervention**

We found a scarcity of mHealth interventions that used change theory as the basis of the content development of the intervention. In fact, Tomlinson et al [21] maintained that nearly all mHealth intervention programs that are based on information transfer only, rather than an intervention that was designed through an iterative dynamic interaction between the system and the user, are more likely to fail at their implementation phase. Throughout the development of the intervention, we

considered several theoretical frameworks for incorporation at different points in the intervention.

### ***The Theory of Planned Behavior***

The theory of planned behavior drives many behavior change interventions in existence today [22]. This theory evolved from the theory of reasoned action, which was proposed by Fishbein together with Ajzen in 1980 [23]. We used the three principle influencing factors proposed by Ajzen [14] of attitude toward the behavior, subjective norm, and perceived behavioral control to guide message selection and focus. For example, in our messaging development, the first norm, behavioral attitude, convinced the participants of the usefulness, worth, and advantages of the proposed behavior.

Within the mHealth domain, Ajzen and Fishbein's theory of reasoned action has also influenced many modern technology acceptance models, such as Davis's technology acceptance model [24,25] and Venkatesh and colleague's unified theory of acceptance and use of technology [26]. These models replaced many of the attitude measures of the theory of reasoned action with the two technology acceptance measures, which are ease of use and usefulness.

### ***The Action Research Approach***

Jacobs and Graham [15] reviewed iterative health behavior intervention development and research methodologies and concluded that the requirements and solutions of these methodologies were evolved through collaboration between the developers and their intended target audiences. They promoted adaptive planning, and evolutionary development and delivery, and encouraged rapid and flexible response to change. This strategy minimizes the overall risk and allows a project to adapt to changes quickly [15]. It further contributes to the participants having an investment in and relating to the messages and intervention that is developed.

### ***The Health Action Process Approach***

The health action process approach (HAPA) proposes a sequence of two continuous self-regulatory processes, a goal-setting phase (motivation) and a goal-pursuit phase (volition). The goal-pursuit phase might be further subdivided into a planning phase, action phase, and maintenance phase. It is claimed that perceived self-efficacy plays a crucial role at all stages, along with other cognitions. For example, risk perceptions serve predominantly to set the stage for a contemplation process early in the motivation phase but do not extend beyond it. Similarly, outcome expectancies are chiefly important in the motivation phase when individuals balance the pros and cons of certain consequences of behaviors, but these expectancies lose their predictive power after a personal decision has been made. However, if one does not believe in one's capability to perform a desired action, one will not adopt, initiate, and maintain it [16].

### **Aims**

To our knowledge, there are some interventions for promoting safe sex within a public health context, but none in the postoperative period after VMMC apart from sending simple text messages. Here we describe a participative, theory-based,

mobile phone, audio messaging intervention attractive to recently circumcised men at VMMC clinics in the Cape Town area in South Africa. We designed the intervention to shift some of the tasks related to postoperative counselling on wound management and goal setting on safe sex. We place the emphasis on describing the full methodology to allow for replication of the method in other health care and prevention areas.

## **Methods**

We conducted this study as part of the formative phase of a clinic-based randomized controlled trial to evaluate the effectiveness of an automated telephone message system on reducing early resumption of penetrative sex among recent recipients of VMMC. The effectiveness of the intervention will be evaluated using a 2-armed, randomized, single-blind, controlled design, where the control group will receive the standard of care and the experimental group will receive the standard of care plus the study's voice message intervention, described below, during the 6-week recuperation period [27].

### **Setting**

The study was conducted in catchment areas of the Heideveld Public Health Clinic and Mitchells Plain Hospital in Cape Town, in the Western Cape Province of South Africa. The study sites were chosen with the help of the provincial health department. The population demographics of these two areas are almost exclusively Coloured and Afrikaans speaking. The term Coloured refers to an official South African race group used in research and census data that is predominantly mixed ancestry. The term originated in the apartheid era but remains an important descriptor and label for a distinct community. More than 48% of the people who live in the Western Cape are classified as Coloured, mostly still living in defined communities that are at least 90% Coloured. Both areas are densely populated, with a low socioeconomic base and an average population density of 9600/km<sup>2</sup>. The housing is typically 1- to 2-bedroom maisonette housing. In 2011, the population of the suburb Mitchells Plain was 310,485 and the average household size was 4.57 people per household. There is a large Muslim population (10% to 15%) in the catchment area for one of the townships [28]. The Coloured community has a growing HIV prevalence rate—7.6% according to the latest antenatal data, indicating a generalized epidemic in this population [29]. The heightened HIV risk to this population group lies in a high illicit drug and alcohol use in the community, which is associated with risky sexual behavior [30].

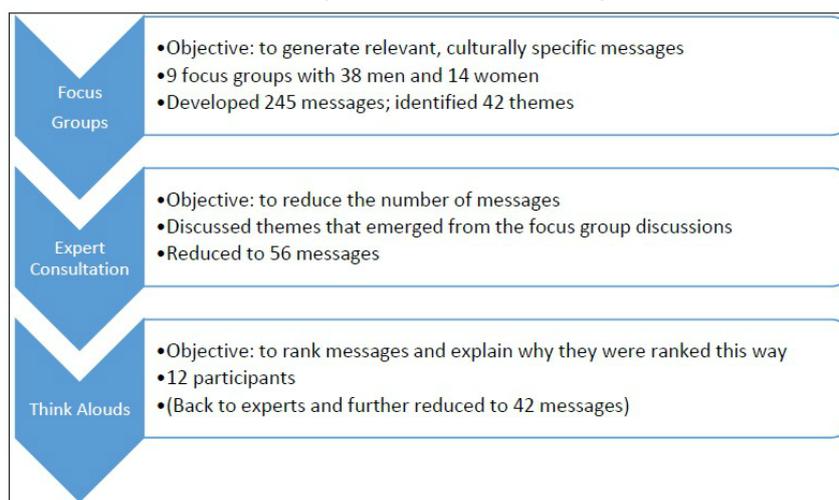
### **Design**

We used several participative, qualitative methods to develop mHealth phone messages and their sequencing, placing the user's needs and experiences in the center. These were (1) focus group discussions with 52 recently circumcised men and their partners to develop initial messages they felt were relevant and appropriate, (2) thematic analysis and expert consultation to select final messages for pilot testing, and (3) cognitive interviews with 12 recent VMMC patients to judge message comprehension and to rank the messages (Figure 1). All

interviews were conducted in Afrikaans, tape recorded, and then transcribed and translated into English.

Message content and phrasing was guided by the theory of planned behavior and HAPA. The methods and incorporation of the theoretical frameworks are described in more detail below.

**Figure 1.** Steps to develop an mHealth intervention for recently circumcised men at voluntary medical male circumcision clinics in South Africa.



### Focus Groups

In order to generate messages that would be considered appropriate and relevant for patients, we conducted 9 focus

groups with a total of 52 men and women (6 male and 3 female focus groups) (Table 1). The methods of recruitment, conduct, and analysis of the focus groups are explained elsewhere [31].

**Table 1.** The study participants of the focus groups by sex and religion.

Focus group no.	Sex	No. of participants	Age range (years)	Religion	
				Muslim	Christian
1	Male	6	19–36	4	2
2	Male	6	22–45	3	3
3	Male	6	23–63	4	2
4	Male	7	18–42	5	2
5	Male	6	20–39	4	2
6	Male	7	21–53	4	3
7	Female	4	22–41	2	2
8	Female	5	19–34	3	2
9	Female	5	25–52	3	2

In addition to providing valuable information about the perceptions and behavior patterns of couples during the wound-healing period [31], participants of these focus groups were asked to write down 5 messages they felt could have assisted them during this period. The facilitators gathered these lists before the group discussions began and the researcher captured and translated the messages. We cleaned this list and identified common themes through use of thematic analysis using Atlas.ti version 7 (Scientific Software Development GmbH). Additionally, we collected information on the general acceptability of mobile messaging, generation of appropriate and relevant messages to recipients of VMMC during their 6-week recovery period, and the acceptable frequency of mobile messages. By getting the respondents to develop the theme list, we were drawing out the relevant issues to improve motivation and reduce blocks to volition, as well as identifying key behavioral, normative, and control beliefs.

### Expert Consultation

The second part of this phase was to solicit expert opinion on the internal reliability and the contextual and cultural applicability of the messages. We consulted with a health communication expert from the South African Department of Health with extensive expertise in safe sex and behavior change, and local knowledge of the population and local conditions. As a first step, we grouped the messages into themes and then deleted incorrect, duplicate, and repetitive messages. Through interrater agreement, we decided on 1 or 2 examples representing each theme. We also adjusted several messages to reflect technical correctness and missing themes such as HIV prevention messaging. This decision was guided by existing theoretical models of behavior change, including the HAPA model. The order and frequency of the messages was guided by the recommendations of the focus groups and expert opinion.

This phase is essential to ensure the accuracy of the messages and their constructive interaction with the health services.

### **Cognitive Interviews**

The third phase of the message development was the validation phase, where we conducted cognitive interviews (“Think Alouds”) with 12 patients to rate the final selection of messages. We recruited a convenience sample of 12 recently circumcised men ages 23–39 years (mean 29.6 years) from the Heideveld and Mitchells Plain clinics to participate in this part of the study. Of these, 5 were Muslim and the rest were Christian. All were Coloured except for 2, who were foreign nationals staying in the area. We recruited men who had completed their 6-week wound-healing period during the previous month. The men were recruited from the 2 clinics’ circumcision intake registries. They were recruited via telephone, and the researcher subsequently interviewed them at convenient places in the community.

We asked the participants to evaluate and rank messages based on their appropriateness and effectiveness in the 42-day wound-healing period. The messages were put in groups of 3–6 messages for ranking purposes. Each message was read out to the participants and then tested for comprehension, such as having the participants repeat the message in their own words. We then probed for the participants’ perception of the aim of each message.

Following each section, we asked participants to reflect on the time period in the 42-day period for which we had designed this group of messages. They were then asked to rank the messages in the group for appropriateness and clarity. Following the ranking exercise, we asked participants, using a think-aloud method, to reflect on message grouping and whether there were any messages missing that could have made a difference, on whether there were any unnecessary and inappropriate messages, and on the reasons why they ranked the group in a particular way. This refined the contributions from step 1, improving the messages in terms of both the theory of reasoned action and HAPA.

## **Results**

### **Step 1: Generation of Messages and Key Information on the Messaging**

We had two goals for this stage: the first one was to get an unprompted set of messages from the recently circumcised men and their partners. We ended up with 245 messages the participants felt would have had an impact on their behavior and attitudes during the 42-day postoperative wound-healing period. The second aim was to solicit group responses to questions around frequency, nature, and order of the messages.

Focus group participants’ suggested messages covered 30 different themes. Some examples were wound and pain management, the roles of rest and family support, erection issues, how to stay healthy, when to resume sex, alcohol use, affirmation, sexual needs of partners, and condom use. Themes could be further grouped into phases and practical versus motivational messages. The latter aspects are described more fully below, since they have an impact on how the intervention

was later designed. The selection of messages covered the dominant areas of the HAPA theory—that is, planning and its components of self-efficacy, goal setting, and action.

### **The 2-Phase Approach**

Participants in all focus groups repeatedly stressed that the 42-day period following the circumcision surgical procedure is roughly divided into a wound and pain management period (the first 3 weeks) followed by the adjustment period. The first phase is characterized by practical issues such as wound and pain management, while the second phase is dominated by motivational and planning issues. Examples of comments from the focus groups are

*[First phase:] I think for the first period, it should be about pain management and how to take care of oneself.* [Male, Muslim, 27 years]

*[Second phase:] Later, anything to encourage me to stay safe would be nice.* [Male, Christian, 32 years]

Examples of participants’ suggested messages in the 2 different phases are

*[First phase:] Rest and don’t do anything strenuous in the first week.* [Female, Muslim, 21 years]

*[Second phase:] You did something great. Be proud of yourself.* [Male, Muslim, 51 years]

### **Practical Versus Motivational Messaging**

Participants also clearly distinguished between 2 different types of messages—practical and motivational—which are also associated with the 2 phases. Thus, *in the first phase*, practical messages are linked to coping themes such as inactivity and rest, wound healing, role of the clinic, and support mechanisms:

*[Inactivity and rest:] Rest! This will help with the wound healing.* [Male, Christian, 24 years]

*[Wound healing:] Don’t mess around with the wound. No home remedies!!* [Male, Muslim, 32 years]

*[Role of the clinic and medication:] If there’s any problem down there, go to the clinic to fix it.* [Female, Muslim, 28 years]

*[Support mechanisms:] Are you having a difficult time? Talk to someone you love. They will understand.* [Male, Christian, 35 years]

Motivational messages, however, which were associated with *the second phase*, were closely linked to themes of safe living, the needs of the partner, and goal setting:

*[Safe living:] I think the messages should be about safe living and making sure you take responsibility for your actions.* [Male, Christian, 45 years]

*[Needs of partner:] Take your time when you are pleasing your partner.* [Female, Muslim, 30 years]

*[Goal setting:] No sex or masturbation for six weeks! [Male, Muslim, 21 years]; Want to be healthy? Look after yourself.* [Male, Christian, 47 years]

### ***Salutogenic Nature of the Messages***

An interesting aspect of the focus groups was the emphasis on positive and inspirational messages as opposed to messages that emphasized disease and negative consequences:

*I would like some inspirational messages.* [Male, Christian, 54 years]

*Start every day with a good attitude.* [Female, Muslim, 24 years]

*Be proud of yourself. You did it!* [Male, Muslim, 30 years]

Thus, the majority of the messages that former patients and their partners suggested were positive and assertive.

### ***Frequency of Messages***

In addition to providing message content, participants were asked about their opinions on how often messages could be sent to them.

Participants were wary of unsolicited and invasive messages:

*If they get too many messages, even if they are good, people won't listen.* [Male, Muslim, 43 years]

*This (the frequency of the messages) is very difficult to calculate. I don't think you want to turn this into spam.* [Female, Muslim, 25 years]

The groups were asked of ways to counter this natural resistance to “push” messaging campaigns. The first strategy given was prior consent:

*I guess if I sign up for it and expect it, then it should be okay.* [Male, Muslim, 20 years]

The other strategy was a clear end-date of the program:

*I don't think men would mind getting messages because they know it's only for a certain period.* [Male, Christian, 31 years]

### **Step 2: Expert Consultation**

In consultation with a health communication expert from the South African Department of Health, we reduced 245 messages to 56. This reduction was done by removing identical or similarly structured messages, and amalgamating messages of a similar theme under one exemplar. An example of this was that the messages “Have lots of rest. It will help with your recovery,” “Rest and sleep. This will help with the recovery,” “Sleep a lot. It will help with the healing,” and “Resting will help with the wound healing” were amalgamated into “Rest! This will help with the wound healing.” We made these decisions based on extensive local knowledge of the population and local conditions, and safe sex and behavior change. [Table 2](#) shows the full set of resultant themes by phase once all the messages were combined into a reduced set of thematic constructs, while remaining responsive to the community's felt needs. One message is provided for each theme as an example.

**Table 2.** Themes and example messages by phase after voluntary medical male circumcision resulting from expert consultation.

Phase <sup>a</sup>	Themes	Examples of messages
1	Inactivity and rest	<i>Rest! This will help with the wound healing.</i>
1	Role of the clinic; wound management	<i>Go back to the clinic after two and seven days so the dressing can be replaced and the wound can be checked.</i>
1	Wound management; hygiene	<i>Use lukewarm water to wash the wound every day. Keep the dressing dry.</i>
1	Wound management; erection issues	<i>Check for any skin tightness when you get an erection.</i>
1	Role of the clinic; wound management	<i>If there is pus coming out of the wound, go to the clinic.</i>
1	Pain management; medication	<i>Don't be brave! Take pain tablets to relieve the pain.</i>
1	Wound management; partner and family support	<i>Are you having a difficult time? Talk to someone you love. They will understand.</i>
2	Self-efficacy and affirmation; goal setting	<i>Want to be healthy? Look after yourself.</i>
2	Self-efficacy and affirmation	<i>You can do it!</i>
2	Partner and family support	<i>Make sure you talk to your partner.</i>
2	Self-efficacy and affirmation; motivation	<i>Did you look after your penis today?</i>
2	Goal setting; healthy living	<i>Regular exercise and healthy diet are essential.</i>
2	Wound management; erection issues	<i>Get rid of that painful erection by urinating frequently.</i>
2	Early resumption of sex	<i>Having sex too early will just set you back!</i>
2	Early resumption of sex; alcohol consumption	<i>Be aware of alcohol. It impedes your judgement.</i>
2	Safe living; condom use	<i>Remember that circumcision does not provide 100% protection.</i>
2	Motivation; goal setting	<i>No sex or masturbation for six weeks!</i>
2	Nonpenetrative sex; sexual needs of partner	<i>Find ways to please your partner without using your penis.</i>
2	Nonpenetrative sex	<i>Loving is not about sex only!</i>
2	Self-efficacy and affirmation; motivation	<i>You are the best!</i>
2	Motivation; goal setting	<i>Regular condom use, knowing your HIV<sup>b</sup> status, and keeping to one partner is the recipe for an HIV-free future.</i>

<sup>a</sup>Phase 1: recovery phase; phase 2: adjustment phase.

<sup>b</sup>HIV: human immunodeficiency virus.

### Step 3: Cognitive Interviews

Think-aloud participants engaged intimately with the messages and generally confirmed the set of themes proposed by the previous step. Their interaction with the messages originated from their own experiences during the wound-healing period and confirmed the elements of motivation and volition as proposed by the HAPA model. Although we previously divided the 6-week period into the initial wound-healing recovery phase during weeks 1 to 3 and the adjustment phase from weeks 4 to 6, we now separated the 6-week period into three 2-week periods for ease of discussion. Some of the comments and recommendations made on each 2-week period of the 42-day recovery period follow.

#### *Messages for Weeks 1 and 2*

This period was dominated by pain and wound management themes, as the participants ranked messages such as “Rest! This will help with the wound healing” and “Do not pull or scratch the wound while it is healing” the highest in their groupings. Toward the end of this period, the patient’s support structure was also given priority: “Are you having a difficult time? Talk to someone you love. They will understand.” The group also

recommended that the frequency of phone messages to patients should be twice a day at the beginning of the period, tapering to once a day after the first 2 days, to provide additional support for the days following the operation.

Messages that scored the lowest among the participants were those that the group found impractical, such as “Check for any skin tightness when you get an erection.” In essence, expert opinion dictates that this is an important first visual check of whether the stitching is not impeding or pulling the skin during erections, and that it should be done as early as possible so any corrective surgery can be done before the wound area heals completely. Participants found this expert-inserted message problematic because, during the preoperative wound-care talk, strong emphasis was placed on the danger of prolonged erection and the tearing of the stitches. Further, patients were instructed how to get rid of erections as soon as they could. Patients found their first erection too stressful to pay proper heed to the message’s instruction. Another message that scored very low during this period was the inspirational message “You can do it.” Participants generally liked the intent of the message but felt that it should come later, and they were more interested in practical advice on how to get through this period.

### ***Messages for Weeks 3 and 4***

The messages in this period reflect the changing priorities of the patient. The wound is practically healed and the patient is going through a period of how to adjust to this new feature, not only sexually, but also aesthetically and the way it feels. Messages with recovery themes, such as “Involve your partner in your recovery period” and “Get rid of that painful erection by urinating frequently,” still scored high, but messages such as “Regular exercise and healthy diet are essential,” reflecting adjustment themes, also received high rankings. Expert-driven messages, once again, scored low. Messages such as “If you have sex before the wound is properly healed, there is a greater chance of contracting STIs [sexually transmitted infections] or HIV” were looked at as too academic and preachy. Motivational messages that were too generic, such as “You did it!,” were scored lower than more practically orientated motivational messages such as “Think about what you are going to do before you do it.” Messages on avoiding penetrative sex were also well received during this period.

### ***Messages for Weeks 5 and 6***

The high-scoring messages in this period revolved around alternative sexual activity, such as “Loving is not about sex only!” and “Take your time when you are pleasing your partner;” validation, such as “You lost the skin! Can you feel the difference?;” and looking-ahead messages, such as “You are planning for your future.” Low-scoring messages, as in the previous period, were those expert-adjusted messages that were perceived as artificially instructive, such as “Regular condom use, knowing your HIV status, and keeping to one partner is the recipe for an HIV-free future.”

## ***Discussion***

We developed a formative research process to develop theory-driven and contextually based mHealth messages to provide additional counselling and support to recently circumcised men during their wound-healing period. We employed a process where the targeted group created the initial messages and then the targeted group, researchers, and communication and health experts collaboratively refined and optimized the message regime for the intended period.

This study’s findings suggest that phone messages should be relevant, positive, simple, few in number, and designed to be contextually appropriate for the intended audience. In order to inform and motivate these men, messages must address the reality of the experiences the men are facing throughout the 6-week period. One method is to directly engage men and their partners in iterative discussions about message design and delivery, and involve them in the development of messages so that messages are relevant and meaningful for the recipients.

A few studies have explored the construction and development of health messages delivered through a mobile device using a multiphased approach with a strong target group participation. Ybarra et al [32], in their aim to develop an mHealth HIV prevention program for adolescent gay, bisexual, and queer men, took the message development through 5 iterations with target audiences contacted in the first phase to test acceptability

of the messages and during the last phase with beta testing. They found, as in our study, that the men preferred positive and friendly content that, at the same time, did not try to sound like a peer [32]. Similarly, Woolford and colleagues [33] explored obese adolescent participants’ perspectives related to weight management messages, and they found enthusiasm for short message service text messages as a strategy to support weight loss efforts among these participants. Importantly, the findings from their study also support our study in that teen participants desired brief, positive, encouraging messages that had a “natural” tone and made specific reference to the teen demographic [33]. Another mHealth weight management program conducted by Hingle and colleagues in 2013 using a multistage youth-participatory approach found similar results [34]. The main difference between our study and the ones mentioned above is that the source of the messages in our study was the target audience and not researchers and experts.

A few studies have used behavioral change theory in the development of messages. Hingle et al [34] developed an mHealth intervention to influence the knowledge, attitudes, and behavior of adolescents on nutrition and physical activity. They used a 3-phased youth-participatory approach to develop and test messages. The first phase was content identification and initial message development, the second was message testing and refinement, and the last phase was pilot testing of a message delivery protocol [34]. Other studies by Bock et al [35] and Ybarra et al [32] also concluded that partnering with the target population in the message development is critical to ensure that a salient final product and feasible protocol are created. The pathologic versus the salutogenic nature of the messages has also been shown as a factor in the rate of acceptance of the mHealth interventions [36,37].

Our study used a participatory approach on two levels to take the needs and views of the target population into account in the development of the messages and the frequency of messages. The first level was on the generation of the messages, which was initiated by the target audience, followed by the reflection of expert opinion on these messages. The next iteration, with a cleaner and more theme-centered set of messages, was evaluated by a group of recently circumcised men for relevance and impact.

This approach recommended the development of a progression of the messages. The formative focus groups told us that the period of 42 days following the VMMC procedure is a series of progressive phases, from the purely physical pain and wound management in the early phase of healing, then to that of adjustment, to how their circumcised penis was looking and feeling, followed by an external adjustment to physical movement and sex drive. The content of the messages needed to reflect this continuous movement through the 42 days. So from more practical messages centered on pain and wound management, messages moved to more inspirational and “planning-ahead” messages.

In this study, we found that applying this theoretically informed approach carefully resulted in message content that was consistent across different recuperation phases. We identified certain key themes that we felt would be useful in the design of

mHealth messaging content, as they may facilitate men's healing rates and perceived self-efficacy to attend the clinic and other healing strategies, reduce or minimize potential fears, and provide an impetus for self-care. These included maximizing content relevancy in messaging, encouraging and validating the patient, and providing content that suggested that immediate support structures such as the man's partner, family, or the health care workers were role players in their own recuperation.

It emerged that using the content suggestions of circumcised patients as the genesis of the program's message development could help build on men's already intuitive sense of healing strategies, their knowledge of the benefits of following clear recuperation methods, and what was acceptable to them. This mix of experience and the knowledge of the benefit of adhering to the healing regimen can be leveraged to get men back to the clinic at their appointed schedule and follow the recommended healing program, with the mobile messages functioning as cues to action.

There was an interesting dichotomy in the messages that experts considered as essential messaging for circumcised men in their wound-healing period, such as countering the perception that circumcision replaces condom use; or standard HIV prevention messages, with the circumcised men's perceptions of what essential messages were. The expert messages scored consistently low in desirability or impact. It could be that the applicability aspect was low because most of the participants sought out the procedure for reasons other than HIV prevention, or it could be that there is an oversaturation of these messages and the low scores merely reflect a natural irritation caused by these "academic" messages. Related to this is the participants' strongly held consensus that salutogenic and caring messages would provide a stimulus to trigger men to take the necessary action to heal properly and refrain from penetrative sexual encounters. The salutogenic model is useful for all fields of health care, especially in the field of health promotion, as it provides a direction and focus, allowing the program to move away from disease and risk factors and to focus on the salutary and seeing the entire person in relation to the disease [36].

## Implications for Research and Practice

This study demonstrates a novel way in which to engage men in conversations about health using a familiar and ubiquitous communication method. Rather than being passive recipients of top-down, expert-driven communications, participants in this study had the opportunity to actively participate in the message design process and engage with health information through informal interactions with experts and with one another, thereby increasing the likelihood that they would adopt the recommended behaviors. Based on our findings, this methodological approach to the development of theory-driven, evidence-based, and culturally appropriate health messages in mobile health interventions could be adapted to other cultural and geographic environments and various health issues. This approach can be used as a model to test and adapt health messages in a variety of mobile health intervention projects within a variety of cultural contexts. It can also be applied to health communication message development more generally.

Additional research is needed to determine whether this approach facilitates technology-based interventions to be an effective, sustainable way to promote healthy lifestyles to circumcised men and have a significant impact on behaviors that place men at increased risk. These messages are being evaluated in a randomized controlled trial among approximately 1200 men in 7 VMMC clinics in Cape Town, South Africa.

## Conclusion

mHealth has the potential to provide a valuable health care service in the context of providing an expanded VMMC in resource-restricted circumstances. To provide this service, we argue that the intervention platform, the message content, and the delivery timing have to be responsive to the felt needs of the respondents, as well as providing good factual information. As with other interventions, mHealth also needs to use established behavioral theories to develop and construct interventions and messages.

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## Conflicts of Interest

None declared.

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## Abbreviations

**HAPA:** health action process approach

**HIV:** human immunodeficiency virus

**VMMC:** voluntary medical male circumcision

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DRAFT

**Title:** Effectiveness of an audio-based cellular platform on increasing safe sexual behaviour during the healing period after male circumcision in Western Cape, South Africa.

**Authors:** Yoesrie Toefy<sup>1,2</sup>, Donald Skinner<sup>2</sup>, Tonya M Esterhuizen<sup>3</sup>, Michael McCaul<sup>3</sup>, Max Petzold<sup>1,4</sup>, Vinod Diwan,<sup>1</sup> Sarah C Thomsen<sup>1</sup>

<sup>1</sup> Karolinska Institutet, Department of Public Health Sciences, Stockholm, Sweden

<sup>2</sup> Stellenbosch University, Faculty of Medicine and Health Sciences, Department of Global Health, Research on Health and Society Unit, Tygerberg, South Africa

<sup>3</sup> Stellenbosch University, Faculty of Medicine and Health Sciences, Centre for Evidence-based Health Care, Biostatistics Unit, Tygerberg, South Africa

<sup>4</sup> University of Gothenburg, Swedish National Data Service and Health Metrics Unit, Gothenburg, Sweden

## Abstract

**Objective:** To assess whether an m-Health intervention based on mobile audio messages decreases the prevalence of penetrative sex among men during their six-week wound-healing period after medical male circumcision in clinics in the Western Cape Province, South Africa.

**Design:** This intervention was evaluated using a two-armed, randomized, single-blind, controlled design. Only the patients were aware of the intervention assignment; while the clinic and research staff assessing patients, as well as statisticians, and authors were blind to the allocation.

**Measurement:** This sample was collected at 12 clinics in urban areas in Western Cape Province, South Africa. Patients were followed up at 42 days after enrolment. Demographic and covariate information were recorded at baseline and at the six-week follow-up visit. Self-reported sexual behaviour was assessed by a self-administered questionnaire at the follow-up visit. The mobile phone platform kept an online register to record all accessed messages throughout the 6 weeks.

**Setting:** Our study is located in the Western Cape, where the Coloured community accounts for 48.8% of the Western Cape's population, with a rapidly rising HIV prevalence rate of 6.2%. The majority of the townships in the Cape Town area are densely populated with a low socio-economic base.

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**Participants:** The study population consisted of all men 18 or older who indicate at the pre-counselling session that they a) possess a mobile phone, b) consent to participating in the study, and c) will be resident in the area for the duration of the intervention period. Between January 2015 to August 2016, 1670 VMMC patients at seven clinics were screened and 1149 men were recruited into the study.

**Intervention:** The intervention consisted of 38 audio messages that were delivered over the 42 days following surgery. The mobile system automatically called participants twice a day for the first two days, once a day for the next four weeks and on alternative days in the last two weeks. The development of the messages and their timing was developed in collaboration with former recipients of VMMC and their partners, and with the help of public health communication experts.

**Main outcome measures:** The primary outcome was occurrence of any (homosexual or heterosexual) penetrative intercourse at any time in the first 42 days after VMMC. Secondary outcomes were the rate of adoption of non-penetrative sexual behaviours in the first 42 days after the procedure, as a marker of unprotected sex, prevalence of self-reported STI symptoms at baseline and 42 days after the procedure, the sexual risk behaviour at baseline and as a control for risk-taking personality, the rate of sexual risk propensity at baseline.

**Results:** There was a slightly larger positive effect in the Intervention Group (152/542 (28.0%) than in the Control Group (173/535 (32.3%)). The difference between the two groups were not statistically significant ( $p=0.071$ ). After adjusting for baseline covariates, self-reported adherence remained significantly better in the audio messages group than the control group. Members of the control group with a higher sexual risk propensity were more likely to resume sex early than similarly risk-taking members of the intervention group.

**Conclusions:** Early resumption of sex after VMMC is common, warranting better counselling. Mobile health technology is one potential tool in the effective public health intervention programmes, especially in resource-strapped environments, but it should be complemented by other methods. This intervention may be most effective amongst patients who indicate higher sexual risk propensity.

**Trial registration:** Ethical approvals for the conduct of the trial were obtained from all participating institutions prior to study initiation (The Health Research Ethics Committee of Stellenbosch University - ref N14/08/108) and is registered in the Pan-African Clinical Trial Registry (PACTR201506001182385).

## Introduction

The challenge to provide equitable and quality healthcare to all its citizens is a central theme to most governments in the world. In most low- and middle-income countries (LMICs), however, chronic healthcare staff shortages and budgetary constraints are common features of public health sectors[1]. In some countries, the public health burden is much larger than other countries. South Africa, for example, has the biggest and highest profile HIV epidemic in the world, with an estimated 6.3 million people living with HIV in 2013 with a national prenatal prevalence of 30.2%.[2]

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Self-care programmes within these sectors have been considered as a viable stopgap measure to address the service delivery challenges within the sector. m-Health – the use of mobile phone technology to deliver health care – has emerged as an important driver of self-care interventions within healthcare [3]. The potential for m-Health interventions to partially compensate for physical clinics in resource-poor areas is enormous,[4] and although m-Health has been shown to be effective in medication adherence, clinical management and behaviour modification,[5] the use of m-Health has primarily been restricted to developed countries.

A few randomised trials evaluating the use of text message reminders to improve medication adherence for people with chronic illnesses have been conducted in LMICs[4], [6]–[8]. Three randomised trials looking at HIV treatment adherence found benefits[9][10] and one found no impact[11][12]. Two recent systematic reviews found suggestive but non-significant evidence for the benefits of text-based m-Health technology[3].With regards to voice messaging intervention programme, a Cochrane review from 2013 found only one RCT of a telephone-delivered intervention in the use of post-exposure prophylaxis (PEP) for rape victims for preventing HIV infection in HIV-negative persons. Voice messaging as an intervention was used effectively in the fields of nutrition and weight-loss and smoking cessation programmes. In Nigeria, a behaviour intervention using a combination of approaches, including voice messaging, were used to change or inforce breastfeeding patterns.[13] A study trying to improve the adherence to diabetes treatment also used VM successfully.[14]

Systematic reviews show that the majority of the mHealth interventions in the public health arena are often not developed in a systematic manner.[15], [16] The gaps in mHealth intervention development stem from the limited scale and scope of mHealth implementation and evaluation[17] and a mismatch with physical environments that does not match health objectives and related metrics to available mHealth tools and systems.[18] The current

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mHealth evidence base comprises mostly evidence from the field of computer science and not health, and this is not sufficient to inform and influence stakeholders to invest resources in nationally scaled mHealth initiatives.[19]

This study deals with the application of a m-Health intervention on a reported adverse public health issue that has emerged from the widespread roll-out of voluntary medical male circumcision (VMMC) programmes in Sub-Saharan African region. Research found that men do not wait until the end of their six-week wound-healing period before engaging in penetrative sex.[20], [21] The importance of medical male circumcision as a form of HIV prevention strategy is highlighted by the fact that the transmission of HIV in South Africa is almost exclusively through heterosexual sex.[22]–[25] The South African Department of Health has made a commitment to rolling out medical circumcision in all provinces as one source of protection from HIV.[26] Approximately 5 million adult men could potentially be targeted. Circumcision is thus provided as part of a comprehensive service at district hospitals, and includes HIV testing, counselling and HIV education before the procedure.[27] We evaluated a mobile-Health self-care intervention that was grounded in the social cognitive theory of planned behaviour (and other change theory) to increase the adoption of safe sexual behaviour during the post-operative period for medically circumcised men in Western Cape Province, South Africa. This paper reports on the effectiveness of the m-health intervention.

## **Methods**

### **Trial design**

This intervention was evaluated using a two-armed, randomized, single-blind, controlled trial. The rationale, study design, and analysis plan of this study have been published previously[28]. Only the patients were aware of the intervention assignment; while the clinic

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and research staff assessing patients, statisticians and authors were blind to the allocation. Allocations were revealed only after the blinded results were analysed and discussed by all authors.

### **Study setting and participants**

Our study is located in the Western Cape, where the Coloured community accounts for 48.8% of the Western Cape's population,[29] with a rapidly rising HIV prevalence rate of 6.2%.[30] The heightened HIV risk to this population group lies at least partly in a high illicit drug and alcohol use in the community, which is associated with risky sexual behaviour.[31] The majority of the townships in the Cape Town area are densely populated with a low socio-economic base. The housing is typically one to two-bedroom "maisonette" housing with an average population density of 9,600 per km<sup>2</sup> and an average house density of 4.57. The community is predominantly Christian but there is a large Muslim population (10–15%) in the townships.[30]

The study population consisted of all men 18 or older who indicated at the pre-counselling session that they a) possessed a mobile phone, b) consented to participating in the study, and c) would be resident in the area for the duration of the intervention period.

### **The mobile phone intervention**

In addition to the standard of care regime offered to all VMMC patients, this group received the intervention programme, which consisted of 38 audio messages delivered over the 42 days following surgery. The mobile system automatically called participants twice a day for the first two days, once a day for the rest of the first four weeks and on alternative days in the last two weeks. Using the last four digits of their mobile number as their password, the participant listened to the message and used their keypad to replay it if they did not

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understand the message. The platform was programmed to redial unanswered or busy numbers up to three times. The platform also allowed the project manager to log on and draw activity reports on participating participants. The development of the messages and their timing was developed in collaboration with former recipients of VMMC and their partners, and with the help of public health communication experts. The timing of the message was guided by the Theory of Planned Behaviour[32] and the Health Action Process approach[33]. More information on the intervention is published elsewhere[34].

### **Standard of care**

This group received the standard of care regime offered by the Department of Health circumcision team. This consisted of the counselling session during the VCT procedure and a brief post-surgery counselling session, where they are advised on how to care for the wound and ordered to go to their local clinic after two and seven days following surgery. They were reminded not to engage in penetrative sex until the mandatory wound-healing period of six weeks has passed. No further contact is sought other than if there were health complications such as swelling or infection of the penis.

### **Randomisation**

A biostatistician generated the two comparison groups using simple randomization, with an equal allocation ratio, by referring to a table of random numbers. Assignment sequences were placed in consecutively numbered opaque sealed envelopes that ensured allocation concealment. The study numbers were allocated consecutively as the patients come into the waiting area and written in the top corner of the envelope, which were handed to the participant.

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## **Study procedures**

This sample was collected at 12 clinics in urban areas in Western Cape Province, South Africa. Patients were followed up at 42 days after enrolment. Demographic and covariate information were recorded at baseline and at the six-week follow-up visit. Self-reported sexual behaviour was assessed by a self-administered questionnaire at the follow-up visit. The mobile phone platform kept an online register to record all accessed messages throughout the 6 weeks. Patients defined as lost to follow-up were those who failed to complete their six-week follow-up visit and were unable to be traced within two weeks of the follow-up visit. We completed a telephone survey of the outcome variable and selected covariates with the cohort that failed to complete the follow-up survey but still fell within the two week post-follow-up assessment extension.

Baseline data was collected after recruitment and before the patient underwent the circumcision procedure and the follow-up data was collected from returning participants to the clinic after six weeks. Sexual behavioural data, from both instances and from all the participants, was collected through a self-administered questionnaire to avoid social desirability bias including self-reported sexually transmitted infections STI symptoms and sexual behaviour history. HIV status was only collected (coded) from files with the permission of the participant and was coded for anonymity. A quality control manager ensured that data entered in the case report forms were complete and accurate. A double data entry system was employed to minimise errors, which was supervised by the project manager. The fidelity of the intervention was monitored continuously throughout the trial by the project manager who had access to the mobile phone intervention software reports that were available on a daily basis.

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## **Statistical analysis**

The statistical analysis plan was specified before the study was unblinded and was reported in the trial protocol.[28] We calculated that a sample size of at least 540 per arm, with a complete study sample of 1,080, would have 90% power to detect a 10% improvement in abstinence as found in previous studies, [20], [28], [35], [36] at 0,05 level of significance.

The likely rate of loss to follow up was assumed to be 10% so the above numbers were adjusted accordingly and inflated by 10% to the effective total sample size of 1,188. Analyses were undertaken on an intention-to-treat basis using SPSS and Stata version 13.1 (StataCorp. LP, College Station, United States of America). The effect of the intervention was expressed as a relative risk (RR); a 95% confidence interval (CI) was used for primary and secondary outcomes. The primary outcome was the occurrence of penetrative sex at any time in the six weeks following the VMMC procedure. The secondary outcomes were i) the adoption of non-penetrative sexual behaviours in the six weeks after the procedure, ii) the prevalence of self-reported STI symptoms, iii) the perception of sexual risk behaviour, and iv) the self-reported level of sexual risk propensity (as a measure of risk-taking personality). The penetrative sexual resumption rate was assessed using Kaplan–Meier survival analysis techniques: for 6-week follow-up data, resumption was assessed in participants who reported resumption of penetrative sex in weeks 1-3, week 4, week 5 and week 6.

## **Ethical considerations**

Ethical approvals for the conduct of the trial were obtained from all participating institutions prior to study initiation (The Health Research Ethics Committee of Stellenbosch University - ref N14/08/108) and is registered in the Pan-African Clinical Trial Registry (PACTR201506001182385).

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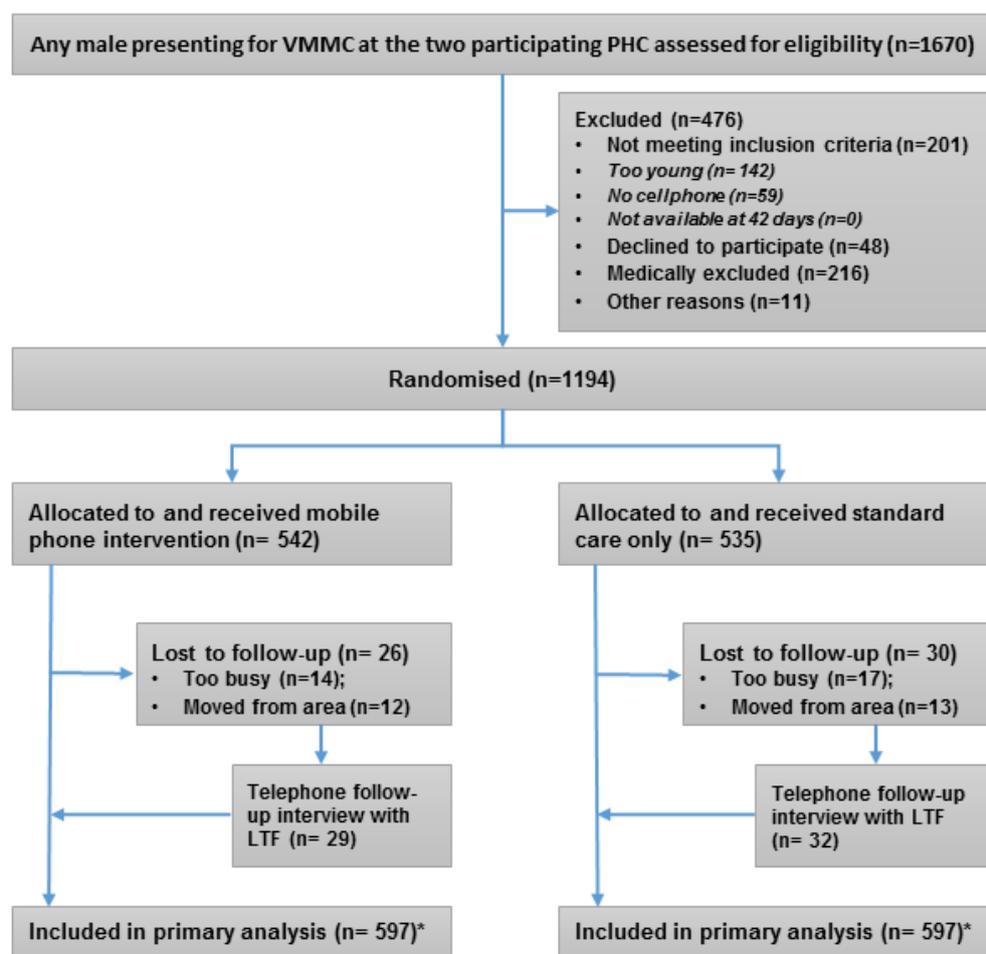
Access to the participants was obtained at the clinics through the provincial department of Health (Reference: RP 100/2013). Written informed consent was obtained from all participants prior to enrolment as required with national requirements and the principles of the Declaration of Helsinki. Confidentiality was maintained at all levels of data management. An independent data safety and monitoring inspection was performed midway through the trial. All staff who came into contact with participants completed a GCP/ethics course.

## **Results**

### **Study sample**

Between January 2015 to August 2016, 1670 VMMC patients at seven clinics were screened and 1194 men (71.5%) were recruited into the study and randomised. 476 (28.5%) patients were excluded from the study prior to randomisation (figure 1) for a variety of reasons. 201 of those did not meet the inclusion criteria (142 patients were too young and 59 had no cellphone). A further 216 were medically excluded from the VMMC procedure by the VMMC team, 48 were not interested in the study and lastly, 11 were excluded for other reasons. After enrolment, 597 participants were randomised to each of the intervention and control arms. At the 42-day follow-up stage, the study could not collect data from 117 participants (9.8%). We followed up telephonically with this lost-to-follow-up group with a shortened questionnaire and we managed to obtain data from a further 61 (29 Intervention and 32 Control) participants. The remaining 56 loss-to-follow-up participants (4.7%) had similar pre-randomisation characteristics (Table 1). The study found 31 participants were too busy to participate and 25 participants moved from the area.

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\* Intention-to-treat design, so all participants included in analysis

Figure 1: Consort diagram

Table 1: Demographics and baseline characteristics

Characteristics	Total	Intervention (n=579)	Control (n=579)
Age of participants (n=1194)			
<b>Age (SD)</b>	29.34 (9.38)	29.78 (9.70)	29.87 (9.04)
<b>18 - 30 yrs</b>	752 (63.0%)	367 (61.5%)	385 (64.5%)
<b>31 – 40 yrs</b>	294 (24.6%)	147 (24.6%)	147 (24.6%)
<b>41 yrs and older</b>	148 (12.4%)	83 (13.9%)	65 (10.9%)
Language (n=1173)			
<b>English</b>	604 (51.5%)	285 (48.7%)	319 (54.3%)
<b>Afrikaans</b>	517 (44.1%)	272 (46.5%)	245 (41.7%)
<b>isiXhosa</b>	38 (3.2%)	24 (4.1%)	14 (2.4%)
<b>Other</b>	14 (1.2%)	4 (0.7%)	10 (1.7%)
Education (n=1161)			

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Characteristics	Total	Intervention (n=579)	Control (n=579)
<b>Primary school or less</b>	60 (5.2%)	38 (6.5%)	22 (3.8%)
<b>High School (not completed)</b>	624 (53.7%)	319 (54.9%)	305 (52.6%)
<b>High School (completed)</b>	477 (41.1%)	224 (38.6%)	253 (43.6%)
Post-matric (n=952)	221 (23.2%)	112 (23.8%)	109 (22.6%)
Marital status (n=1176)			
<b>Not married and not living with a partner</b>	619 (52.6%)	296 (50.6%)	323 (54.6%)
<b>Married and not living with a partner</b>	88 (7.5%)	49 (8.4%)	39 (6.6%)
<b>Not married and living with a partner</b>	72 (6.1%)	38 (6.5%)	34 (5.8%)
<b>Married and currently living with partner</b>	223 (19.0%)	112 (19.1%)	112 (19.0%)
<b>Divorced/Widowed</b>	173 (14.7%)	90 (15.4%)	83 (14.1%)
Not living with partner (v Living with partner) (n=1176)	881 (74.9%)	436 (74.5%)	445 (75.3%)
Unemployed (v Employed) (n=1128)	573 (50.8%)	279 (50.4%)	294 (51.2%)
Religion (n=1172)			
<b>Formal Churches</b>	479(62.3%)	235(63.9%)	244(60.84%)
<b>Charismatic Churches</b>	106(13.8%)	51(13.9%)	55(13.7%)
<b>Muslim</b>	167(21.7%)	78(21.2%)	89(22.2%)
<b>Other</b>	17(2.2%)	4(1.1%)	13(3.2%)
Type of dwelling (n=1144)			
<b>Homeless or shack dweller</b>	150 (13.1%)	81 (14.2%)	69 (12.0%)
<b>Room in hostel or garage</b>	100 (8.7%)	49 (8.6%)	51 (8.9%)
<b>Flat or house</b>	894 (78.1%)	441 (77.2%)	453 (79.1%)
<b>Told you have an STI at Baseline(n=1118)</b>	196 (17.5%)	111 (19.8%)	85 (15.3%)
<b>Self-reported HIV positive status at post evaluation</b>	87 (9.70%)	43 (9.70%)	44 (9.70%)

There was a slightly larger positive effect in the early resumers of the intervention group (152/542 (28.0%) than in the control group 173/535 (32.3%)) (table 2). Therefore, patients who did not receive the audio messages were 1.16 times as likely to engage in penetrative sexual encounters in the post-op period as patients who received audio messages. This finding was not statistically significant ( $p=0.103$ ). After adjustment for those baseline variables for which there seemed to be differences between the two groups, only alcohol use

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(high) and levels of anxiety (high) were found to be associated with the early resumption of penetrative sex in the recovery period (Table 2).

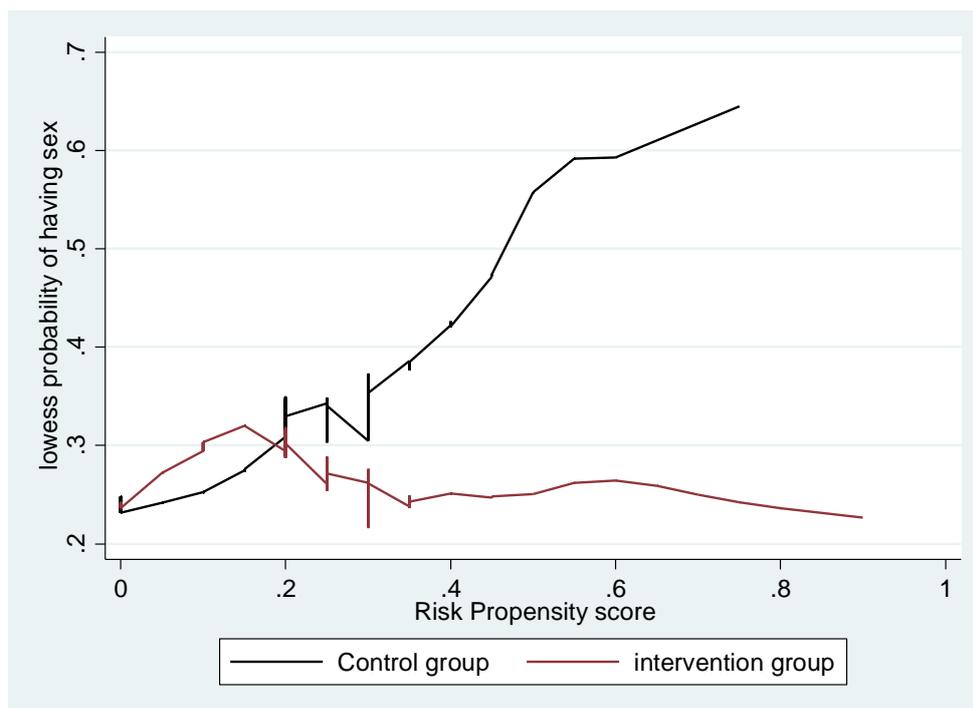
Table 2: Primary outcome: Early resumption of penetrative sex and covariates

	Audio message group (number [%])	Control group (number [%])	RR (95% Confidence Interval)	P value
<b>Primary outcome</b>				
<i>Intention-to-treat analysis</i>				
Had one or more penetrative sexual intercourse in the six week recovery period	152 (28.0%)	173 (32.3%)	1.16 (CI: 0.97-1.39)	0.103
<i>Complete-case analysis</i>				
Had one or more penetrative sexual intercourse in the six week recovery period	158 (27.7%)	182 (32.1%)	1.11 (CI: 0.98-1.28)	0.103
<b>Covariates</b>				
Alcohol use (Yes)	410 (67.8)	412 (69.0%)	1.28 (CI: 1.04-1.58)	0.018
Anxiety level (High)	111 (49.78)	121 (22.7)	1.007 (CI: 1.0007-1.0132)	0.029

Table 3: Generalized linear model on early resumption of sex between the two study groups with an interaction of sexual risk propensity

Reported early resumption of penetrative sex	RR	EIM Std. Err.	z	p> z	95% Conf. Interval	
					Lower	Upper
Randomization	1.216	0.241	0.99	0.324	0.825	1.792
Sexual risk propensity	3.908	2.027	2.63	0.009	1.414	10.799
Randomization X Sexual risk propensity	0.197	0.144	-2.22	0.027	0.047	0.828
Constant	0.237	0.035	-9.83	0.000	0.178	0.316

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*Figure 2: Interaction of propensity score on reported sexual activity*

The relative risk for sexual risk propensity was 3.91, which was the increase in risk for sexual activity with a one unit increase in propensity score for the control group (Table 3). The interaction risk ratio was 0.197, which is the difference in risk ratios between the intervention and control groups ( $p=0.027$ ). This means that the effect of the sexual risk propensity on early resumption of penetrative sex in the recovery period was different for the intervention and control groups. In the control group risk propensity increased the participants' likelihood of having sex, while in the intervention group there was minimal influence of risk propensity on early resumption of sex. Figure 2 confirms this interaction graphically between the participants' propensity score and their level of penetrative sexual activity.

We found (Table 4) that patients who did not receive the audio messages had 26% less risk of engaging in non-penetrative sexual encounters in the post-op period compared to patients who received audio messages. This finding was statistically significant ( $p=0.009$ ). While controlling for self-reported one or more penetrative sexual encounter in their recovery period and reported high sexual propensity risk scores (Table 5), patients who did not receive the

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audio messages were 26% less likely of reporting one or more non-penetrative sexual encounter in their recovery period compared to patients who received audio messages. This finding was statistically significant ( $p=0.013$ ).

Table 4: Secondary outcomes

	<b>Audio message group (number [%])</b>	<b>Control group (number [%])</b>	<b>RR (95% CI)</b>	<b>P value</b>
<b>Secondary outcomes</b>				
Non-penetrative sexual encounters (reported)	111 (20.5%)	90 (16.8%)	0.74 (CI: 0.59-0.93)	0.009
STI symptoms (at least one)	210 (40.4%)	185 (36.5%)	1.13 (CI: 0.81-1.58)	0.73
Sexual risk behaviour	204 (38.6%)	197 (36.8%)	0.95 (CI: 0.82-1.11)	0.542
Sexual risk propensity (low to high risk)	488 (88.9%)	522 (92.6%)	1.64 (CI: 0.80-3.33)	0.174

Table 5: Occurrence of non-penetrative sexual encounters

<b>Occurrence of non-penetrative sexual encounters</b>	<b>RR</b>	<b>EIM Std. Err.</b>	<b>z</b>	<b>p&gt; z </b>	<b>95% Conf. Interval</b>	
					<b>Lower</b>	<b>Upper</b>
Randomization (Control Group)	.743	.088	-2.50	0.013	.589	.938
Reported penetrative sex (Yes)	4.134	.545	10.76	0.000	3.193	5.354
Propensity Personal Scale	1.257	.579	0.50	0.620	.509	3.102
Constant	.106	.017	-14.01	0.000	.077	.145

We also conducted a survival analysis on the time to resumption of penetrative sex of the participants and found that there was no significant difference between the two groups (Log rank: 2.77,  $p: 0.096$ ) (table 5). The mean time to sexual debut in the intervention group was 5.81 weeks and in the control group it was 5.8 weeks. Amongst those who reported penetrative sex during the six-week recovery period, 48.2% of the intervention group and 50.9% of the control group engaged in sex between week 3 and week 5 of the recovery period (table 6).

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*Table 5: Means for time (in weeks) of penetrative sexual debut within the six-week recovery period*

Randomisation Groups	Estimated Mean	Std. Error	95% Confidence Interval	
			Lower Bound	Upper Bound
Intervention	5.805	.025	5.755	5.854
Control	5.797	.023	5.752	5.842
Overall	5.801	.017	5.768	5.834

*Table 6: Time to sexual resumption after MMC*

Penetrative sexual debut after MMC	Intervention	Control	P value
In the first 3 weeks after surgery	10 (6.6%)	5 (2.9%)	0.105
In the fourth week after surgery	17 (11.2%)	14 (8.1%)	
In the fifth week after surgery	39 (25.7%)	63 (36.4%)	
In the sixth week after surgery	71 (46.7%)	79 (45.7%)	
<i>Missing</i>	15 (9.9%)	12 (6.9%)	
Total early resumers	<b>152 (100%)</b>	<b>173 (100%)</b>	

### Fidelity of the intervention

A high level of intervention fidelity was maintained during the trial. The mobile phone monitoring reports of the total number of calls that went out to all patients in the intervention arm indicated that 99% of scheduled calls went through, and 87.3% of these calls were received by patients.

### Discussion

To our knowledge, this was the first randomized trial to evaluate an audio messaging m-Health system to improve post-operative counselling to recovering VMMC patients. We found that exposure to the audio messaging system led to a modest decrease in the occurrence of penetrative sex compared to a control group who only received standard face-to-face care (28% vs. 32.3%), although the difference was not significant. We also found that the reporting of penetrative sex within the 6-week recovery period was associated with higher

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alcohol use and anxiety levels. We found a statistical trend suggesting that the presence of sexual risk factors such as the presence of at least one STI symptom and a self-perceived HIV infection risk, as well as a high sexual risk propensity self-rating were independently associated with the higher incidence of penetrative sexual encounters during this period.

We also found that the level of sexual risk propensity has a greater effect on those who did not receive the intervention than those who did. The sexual risk propensity scale is used as a measure of an individual's risk-taking behaviour through asking questions about behaviours associated with higher risk for STI such as engaging in sex with sex workers, having unprotected sex with more than one partner, and having concurrent partnerships. The full 18-item scale was tested by Mattson (2010) in the original clinical trials looking at the effectiveness of medical male circumcision in Kenya. In that setting, the scale demonstrated very good item reliability, it was unidimensional, and was associated with higher prevalence of STIs in the clinical trial participants.[37] Our study showed a clear interaction effect between the probability of engaging in sexual activity early and sexual risk-taking personality of the control group who did not receive the m-Health intervention. Thus, the intervention seems to have been effective in reducing risk-taking behaviour amongst men with higher risk at baseline. This indicates that if MMC patients were screened for risk-taking behaviour at the pre-operative phase, the intervention could potentially be offered only to those who display a sexual risk-taking personality and that could prevent even riskier behaviour than what we saw amongst those who received the intervention.

The audio message group reported a significantly higher uptake of non-penetrative sex than the control group in this study. This is not surprising since the audio messages stressed trying this rather than full penetration. Messages such as “please your partner” and “find ways to please your partner without using your penis” were introduced from week five. The messages were generated by patients and their partners themselves, who stressed a more salutogenic

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approach than public health officials did,[38] and the timing was informed by the Health Action Process Approach, which stresses a phased approach to public health messaging.[33] Although messages stressing complete abstinence were much more frequently transmitted than these salutogenic messages, it is possible that the participants simply were too aroused by non-penetrative sex to be able to stop. On the other hand, survival analysis showed that half of the early sexual resumption that occurred in *both* the intervention and control groups' took place in the last week, indicating that the intervention probably did not indirectly affect early resumption of sex in that period.

What is more worrying is that 12% of the early resumers did so in weeks 3 and 4. The World Health Organization defines clinical healing after an VMMC procedure as the presence of an intact epithelium (unbroken skin) covering the penial wound with no sutures, scabbing, drainage, moisture, gaps between epithelial edges or ulceration.[39] At weeks 3 and 4, the newly formed epithelium around the wound is still vulnerable to tears and lesions during the stresses the penis undergoes during penetrative sex, which could lead to increased risk of STIs in both men and their partners.[40]

Circumcision appears to be a simple intervention, but there are clear challenges that need to be considered, in particular appropriate and feasible counselling around the post-operative period is essential. Our study showed that 30% of the participants engaged in sex during the recovery period, and amongst these, nearly 50% of them had sex before Week Five. Hewett et al (2012) found similar results and estimated that if 61,000 Zambian men were circumcised in one year, early resumption of sex would result in 69 extra HIV infections (32 in men and 37 in women), although this would be less than the 230 infections that would have resulted if these men had not been circumcised.[20] It may be that the men who resumed sex early (ie before week six) perceived that they were fully healed. In the absence of a clinical control it is not possible to know. However, our formative research indicates that men do have sex

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early, even when the wound is unhealed, and that one risk factor is alcohol use.[42] This is confirmed by the results from the current study that shows that alcohol use is independently associated with penetrative sex in the healing period, even when controlling for other risk factors like risk propensity. Thus, there is still a need for counselling strategies that address this behaviour.

Likewise, the use of m-Health has to go beyond the simple delivery of information. There is a need to consider how the messages are received and internalised, especially in a context of mass of information that people are exposed to. Information development needs to consider both existing theory, and the needs and preferences of those who will be receiving the messages. Our intervention was developed and validated with patients and their partners – and was based on behaviour change theories such as the Theory of Reasoned Action – and yet it still did not affect behaviour. Odeny et al. (2012) investigated the effect of text messaging to deter early resumption of sex among recently circumcised men in Kenya through a two-arm parallel-randomized controlled trial and also found no statistical difference in early resumption of sex between the intervention and control groups.[43] It is possible, that this intervention could be effective on VMMC patients who have a sexual risk-taking personality, although this should be tested in a separate study that is appropriately powered for this hypothesis.

### **Study Limitations**

Despite the randomized trial design, and our endeavour to ensure a high degree of internal validity by random assignment, use of robust outcome measures, blinded assessment of adherence values, and pre-specified blinded analyses; the findings from this study must be interpreted in the context of a number of limitations.

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These limitations include the lack of black participants in the study, who have traditionally been pegged as the higher risk to HIV infection.[44] The lack of uptake of VMMC among the Xhosa-speaking community is well documented [44], [45] and the main premise of the development of the intervention centred on it being a culturally tailored intervention. Once the intervention's efficacy has been proven, cultural adjustment could be made to the content of the messages to target this grouping. Another limitation is that participants without a mobile phone were excluded from the study as well as persons under the age of 18. The possession of a mobile phone as an inclusion criterion was central to the delivery of the m-Health intervention. Reviews from within the cell phone industry and m-health studies have shown that the penetration of mobile phones, especially in this population demographic, is nearly universal. Our study reported that out of the 1670 participants we approached to participate on the study, we only had to exclude 59 participants (3.5%) for not having a mobile phone. With regards to the age limitation, we acknowledge that risk to HIV and other STI exposure is not restricted to a legal-age status, but the ethical procedure for recruiting minors would have necessitated an additional tier in the study population.

The study also proposed to introduce the behaviour intervention to only the randomly selected intervention group with no plans to offer it to the control group for obvious logistical reasons. It remains, however, an ethical dilemma that a group with the same risk profile as those receiving the intervention, are denied access to it. This limitation is regrettable as the intervention is time-bound and it was not possible to offer this intervention to the control group after exiting the study since they will already have passed the 6-week message period. It would be preferable to have an extended follow-up period.

The final limitation revolves around incentivising study participation as incentives are given to all study participants at Baseline assessment (\$7) as well as when they come back for the post-intervention assessment (\$10). The challenges of incentivising participants for

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participating in research are very well documented and debated.[46] We followed Good Clinical Practice (GCP) guidelines on this matter and we made sure that the participants were very well informed of their rights when they were recruited into the study. The ethics committee of the University of Stellenbosch determined that the amount was not coercive in this setting.

Both the control and intervention groups are interviewed to counter the so-called Hawthorne effect. There may be more motivation to change behaviour simply by receiving phone messages (as opposed to the content itself) but if phone messages change behaviour this is an acceptable public health outcome. We have not considered other outcomes such as HIV and STI incidence because to accommodate such events requires a very large sample size and because of the limited follow-up period. Furthermore, there is no financial or ethical rationale for including medical outcomes given that the relationship between unprotected, penetrative sex in the 6-week period after MMC and HIV acquisition has already been established[43]. Therefore, it was deemed sufficient to only collect behavioural data.

## **Conclusions**

The main result of this study indicate that the implementation of an m-Health intervention to supplement existing post-operative counselling with recovering VMMC patients leads to a reduction in the incidence of early penetrative sexual encounters. The fact that, even after careful pre-trial planning around the needs and requirements of the target audience and the clinical environment, the development of a theory-based, participant-driven m-Health programme and a rigorous and robust trial methodology, the positive effect of the intervention remained statistically non-significant, tells us that m-Health strategies cannot be used in isolation to effect behaviour change. In this instance, it must be used in conjunction

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with other counselling and support programmes to safeguard men's health during this recovery period.

Post-operative counselling strategies must be tailor-made to the participants they are targeting. If patients with high risk-taking personalities can be identified through the VMMC clinical uptake procedures via a brief 3-5 item questionnaire, these patients could then be enrolled in more intensive and sustained counselling sessions.

The study also identified the specific weeks in the recovery period that patients reported most of the sexual incidences. Weeks 5 and 6 accounted for 88% of the incidences of early penetrative sexual encounters. Targeted programmatic interventions could be designed to concentrate on this period of the VMMC patients' recovery period.

Finally, it is essential to recognise that the potential, despite the lack of statistical significance of this finding, of m-Health programmes in developing countries' healthcare systems. We need to see mobile technology as a potential tool in the development of effective public health intervention programmes, especially in resource-strapped environments.

**Contributors:** YT helped designed the data collection tools, trained the staff, monitored data collection, supervised data collection at the clinics, analysed the data and drafted the paper. DS coordinated the collaborative trial, , trained staff and gave input on data collection tool design, provided critical input for the analysis plan and manuscript draft, and is co-guarantor for the trial. ST designed the study, also coordinated the collaborative trial, provided input on the study plan, , and provided input to the manuscript and is co-guarantor for the trial. TE, MM and MP wrote the analysis plan, and supported data analysis and the revision of the draft paper. VD provided guidance on the study design analysis and drafting the paper. All authors have approved the final submission.

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**Ethical approval:** Ethical approval for the trial was obtained from all participating institutions before study initiation. In accordance with national requirements and the principles of the Declaration of Helsinki, written informed consent was obtained from all participants before enrolment.

**Data sharing:** Data would be made available on request.

**Transparency:** The authors had full access to all of the data (including statistical reports and tables) in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. The guarantor, on behalf of all the authors, affirms that the manuscript is an honest, accurate, and transparent account of the study being reported, and that no important aspects of the study have been omitted, and that all the changes of the study plan have been explained fully and justified.

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**Supplementary tables**



IV



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## **An evaluation of an audio-based m-Health platform designed to reduce penetrative sex for recently circumcised men during the six-week recovery period**

Yoesrie Toefy<sup>1,2\*</sup>, Donald Skinner<sup>2</sup>, Sarah C. Thomsen<sup>1</sup>

1 Karolinska Institutet, Department of Public Health Sciences, Stockholm, Sweden, 2 Stellenbosch University, Department of Interdisciplinary Health Sciences, Tygerberg, Cape Town, South Africa

\* [ytoefy@sun.ac.za](mailto:ytoefy@sun.ac.za)

### **ABSTRACT**

**Objective:** This study evaluated the patients' perceptions of the platform of an m-health intervention programme designed to reduce penetrative sexual encounters among medical male circumcision patients during their six-week recovery period.

**Methods:** In the course of a multi-clinic study, 1179 circumcision-seeking adult males participated in a 6-week randomized controlled trial. At follow-up, 597 participants completed questionnaires regarding the usability and user experience of the mobile audio platform. Usability was measured with the System Usability Scale (SUS). Five focus groups with a total of 25 patients were also conducted.

**Results:** During the quantitative assessment, participants evaluated the usability of the system with an overall score of 62.80 (SD 13.41) out of 100, which suggests low usability score for the platform. The scale's multidimensionality was shown with the emergence of three trends that explained more than 65% of the total variance of the scale. Results from the focus groups suggest that the experiences of the participants with the m-Health instrument varied greatly. Most of them were positive about the messages and some felt that the content's volume became intrusive and has to be scaled back to be more efficient.

**Discussion:** Reactions to the m-Health tool was generally positive, but medium to low system usability scores, as well as the perceived intrusiveness of the programme and contextual themes indicated a need for a re-adjusting of the m-Health tool. Our methods can assist others in identifying areas in need of improvement.

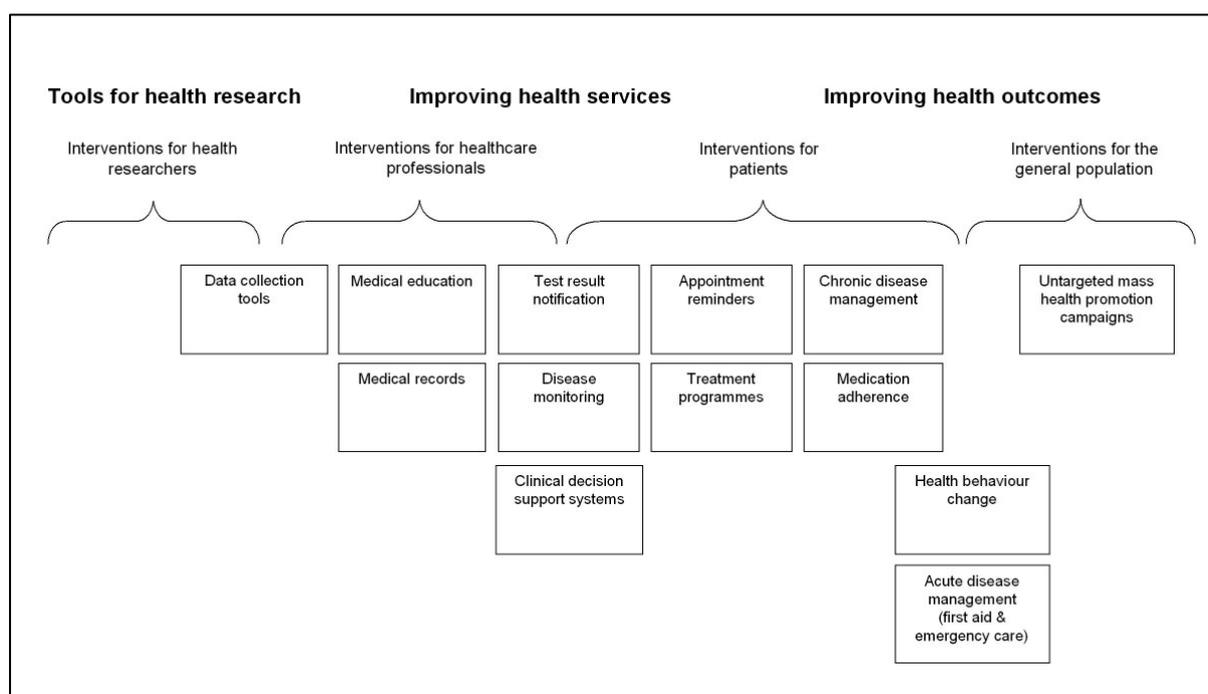
**Conclusion:** The results suggest that the audio messaging system has good usability, user experience and user acceptance. It will be important to take these along with factors such as motivation, gender and age into consideration when designing and further developing ICT-based prevention systems.

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## Background

The challenges that face public health sectors in developing countries to address service delivery to its citizens are considerable and diverse,[1] and centre around chronic staff shortages and expertise, as well as budgetary constraints. Due these challenges, m-Health – the use of mobile phone technology to deliver health care – has emerged as an important and appreciated complement to health care education delivered to complement traditional healthcare channels.[2] In Figure 1 below, Chib et.al categorise m-Health interventions into either tools for health researchers to gather accurate data from the field, instruments designed to improve health services or instruments to improve health outcomes.[3]

Figure 1: m-Health uses in the field



Ref: A. Chib, M. H. van Velthoven, and J. Car, 2014

In South Africa, for example, cell phone technology has been found to be viable for health services, self-care programmes and feasible for HIV and AIDS-related prevention and services, [4]–[6] as there is near universal ownership of cell phones. Consumer studies have shown that 97% of households have a cell phone with a greater concentration of ownership in the urban centers. This ownership and access to mobile phones has very little correlation with income levels.[7]

When evaluating the ‘success’ of an m-Health programme, it is necessary look at its two broad areas of expected performance. The first area deals with the content of the programme and how ‘successful’ it was in achieving what it set out to do, from being simply data-gathering tools for research,[8] to supporting the management of diseases such as diabetes, hypertension, asthma, eating disorders and HIV treatment[9]–[13]; or improving medication adherence for people with chronic illnesses.[9] The majority of m-Health programme assessments concentrate in this first area of performance.[16] Assessing m-Health programmes via its content has been mixed. Three randomised trials looking at HIV treatment adherence found benefits[17][18] and one found no impact[19][20]. Two recent systematic reviews found modest and suggestive evidence for the benefits of text-based m-Health technology.[2] Even the impact and perceived efficacy of individual

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messages varied within a single intervention m-Health programme. In a qualitative study by Toefy et al (2016), results messages at the beginning were perceived as more effective and had a higher approval rate than the messages towards the end of the programme.[21]

The second area of performance is the evaluation of the platform that is used to deliver the programme's content. Adequate usability of an m-Health platform is an essential part of a m-Health programme's overall success. Usability testing is defined as "The extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency and satisfaction in a specified context of use." [22] The purpose of usability testing is to determine obstacles to effective and efficient product use as well as product acceptability and satisfaction for representative users as they interact with the intervention in a specific context.[22]–[24]

There are validated assessment tools that are available to ensure that not only the content of the messages is relevant and impactful, but that the application of the m-Health systems is also suitable and efficient. Research has shown, however, that these tools are not widely used in health care yet. An October 2014 review of usability testing studies on m-Health technology for diabetes showed great variations in usability testing methods. The review found that out of 23 studies, only four used a validated instrument and only one followed a completely standardized procedure including the use of validated instruments.[25] Given the volume of m-Health applications and inadequate usability assessments, the potential impacts on the m-Health systems in terms of user interactions are not clear but are likely to vary substantially which is why assessments like these are important.[25]

This study forms part of a larger study that was designed to evaluate an m-Health intervention that was designed to minimise the incidence of penetrative sex by VMMC patients during their six-week wound recovery period. The m-Health intervention was developed using a staggered qualitative methodology. Starting with an initial quarry of messages generated by VMMC patients and their partners, these messages were analysed by a public health content expert and finalised through a pilot study.[21] They were evaluated using a two-armed, randomized, single-blind, controlled design. The rationale, study design, and analysis of this study have been published previously.[26] The platform was designed to deliver 38 messages on a pre-determined schedule over the six-week period. The platform would send the messages to the participants, resend them three times if the first attempt was unsuccessful and keep a record of programme adherence of all the participants. (This tool is available as freeware on request) In this paper, our goal was to assess the usability of this platform by combining the responses to an established psychometric usability assessment tool, the System Usability Scale (SUS), with the qualitative data from focus groups where the participants were asked about their satisfaction with their interaction with the mobile phone messaging system. We find it essential to consider both the evaluation of the platform of the intervention as well as content of the programme to evaluate the programme adequately.

## **MATERIALS AND METHODS**

We used a combination of qualitative and quantitative methods to explore the user's experience of the m-Health tool.[27]

### ***Setting***

The research was conducted in catchment areas of seven public health clinics with medical male circumcision (MMC) clinics in Cape Town region of the Western Cape Province of South Africa. The communities in the catchment area of the clinics are almost exclusively Coloured and Afrikaans-

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speaking. The term Coloured refers to an official South African race group that is predominantly mixed ancestry that is used in research and census data. All areas are densely populated with a low socio-economic base with an unemployment rate of 20.9% [28] and an average population density of 9,600 per km<sup>2</sup>. [29] The Coloured community, has a growing HIV prevalence rate—7.6% according to the latest ante natal data, indicating a generalized epidemic in this population. [30] The heightened HIV risk to this population group lies in a high illicit drug and alcohol use in the community, which is associated with risky sexual behaviour. [31]

## ***Recruitment***

### **m-Health platform**

As per the trial protocols of the main trail, after completing the informed consent, participants were randomised into either the intervention or the control groups. In addition to the standard-of-care counselling done by the clinic staff, the intervention group received 38 audio messages via their mobile phones over the six-week recovery period. [26] The site manager would register participants randomised to the intervention group, onto the platform via an online dashboard, on the same day of their circumcision procedure.

### **Survey**

All participants completed a baseline survey at the beginning of the study and a follow-up survey after six weeks. The SUS scale was included in the follow-up survey and was completed only by participants in the intervention arm.

### **Focus groups**

When the study team quality-checked the completed survey, and found that the SUS scale was completed, they proceeded to recruit the participant for the usability focus groups. Using a convenience sampling method, 25 men who received the m-health intervention and completed the follow-up survey were recruited in this manner. Five focus groups were then conducted at the clinics between May and June 2016 with a total of 25 Coloured men from the Woodstock and Delft clinics. The participants' ages ranged from 18 to 54 (mean: 34).

## ***Data collection tools***

### **The SUS usability scale**

The SUS usability scale instrument was developed by John Brooke in 1986, as a reliable, low-cost usability scale that could be used for global assessments of systems usability. [32] This scale, originally developed for the industrial engineering field, has since been applied to a wide variety of products and services, including hardware, software, mobile devices, websites and applications in the medical field. [33] The SUS has been evaluated for validity, reliability, and sensitivity, although not in the current population. [32]–[35] This 10-item Likert scale instrument is administered immediately after the conclusion of the intervention programme and allows users to record their initial feelings and responses about the programme. The ten questions are:

1. I think that I could use this system frequently
2. I found this system unnecessarily complex
3. I thought this system was easy to use

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4. I think I would need the support of a technical person to be able to use this system
5. I found the various functions in this system were well integrated
6. I found there was too much inconsistency in the system
7. I would imagine that most people would learn to use this system very quickly
8. I found this system very cumbersome to use
9. I felt very confident using the system
10. I needed to learn a lot of things before I could get going with the system

The instrument items have a range of 0–4 and the scores range from 0 to 100 which provides a clear estimate of overall usability of the intervention.[32], [33] The scores were calculated according to scale’s guidelines.[32] This consisted of summing the scores on each of the 10 individual items. The values of the negative items 2, 4, 6, 8, and 10, were subtracted from 5 and the positive items were reduced by one and the final sum of all scores was then multiplied by 2.5 to get the overall satisfaction value out of 100. Scores of above 68 are considered to be acceptable or good while scores of 85 or above indicate a high level of usability or excellent score. Scores of 50 or below indicate poor or unacceptable usability.[36]

### **Focus groups**

The discussion guide was designed to gather information from the men on their opinions on the frequency and content of the messages, whether they found the tool itself as intrusive and whether it had any impact on their behaviour and attitudes.

All interviews were conducted in Afrikaans, tape recorded and then transcribed and translated into English.

### **Statistical Analysis**

Statistical analyses were performed using IBM SPSS Statistics 24 for Windows.[37] All outcomes were inspected for normal distribution using histogram plots including normal curves and normal probability plots, and Shapiro-Wilk tests, prior to selection of appropriate statistical tests. Descriptive statistics (mean with standard deviation (SD) for normal distributed outcomes, or median with interquartile range (IQR) for non-parametric outcomes) were used to describe the participant characteristics and all outcome measures. A factor analysis using a Principal Component Analysis extraction method with a Varimax rotation, Cronbach alpha coefficient and  $\chi^2$  were computed. We then used the qualitative data to confirm the analysis.

### **Ethical aspects**

Ethical approval for the trial as a whole, as well as the focus group sub-study, were obtained from all participating institutions prior to study initiation The trial is registered in the Pan-African Clinical Trial Registry (PACTR201506001182385) and the Health Research Ethics Committee of Stellenbosch University (ref N14/08/108).

## **RESULTS**

### ***Message delivery***

The mobile phone monitoring reports of the total number of calls that went out to all patients in the intervention arm indicated that 99% of scheduled calls went through, and 87.71% of these calls were received and acknowledged by patients.

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### Usability scale

The average SUS score for the whole group was 62.80 (SD 13.41) indicating a marginal satisfaction rating across these mHealth system users as seen in Figure 1. However, wide variations in scores existed with a low value of 27.5 and high score of 87.5 with a range of 60-points (Figure1). The spread of the scores shows that 50% scored 60 points and below and the top third percentile scored 75 points and below.

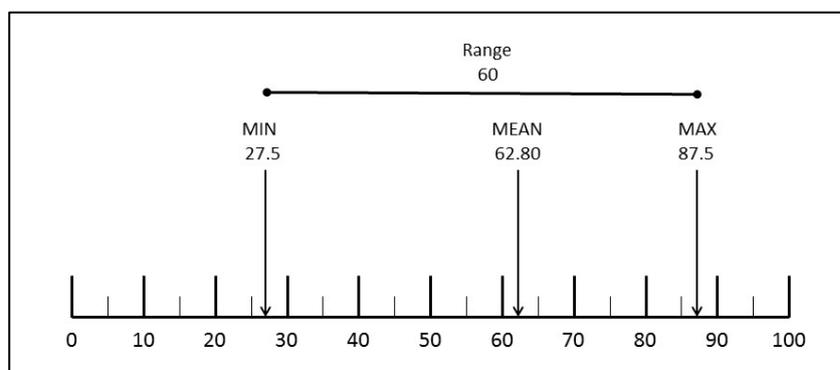


Figure 1: Spread and range of the study population

On individual level, 207 (38%) participants rated usability over 70%, which means that the technology will have good to excellent chances for acceptance in the field, whereas 93 (17%) participants scored SUS below 50 % which indicates an intervention that will probably have usability difficulties.

We did not find any significant differences in the participants when we compared the usability rating scores with the main demographic variables of the men in the study. Foreign language users (86.0, 13.99) and room and garage dwellers (79.39, 13.02) had slightly higher usability scores than their counterparts.

### Factor Analysis

Table 2: Factor Analysis: Total Variance Explained

Component	Initial Eigenvalues			Extraction Sums of Squared Loadings*			Rotation Sums of Squared Loadings		
	Total	% of Variance	Cumulative %	Total	% of Variance	Cumulative %	Total	% of Variance	Cumulative %
1	2.956	29.559	29.559	2.956	29.559	29.559	2.886	28.864	28.864
2	2.482	24.818	54.377	2.482	24.818	54.377	2.137	21.368	50.232
3	1.257	12.566	66.943	1.257	12.566	66.943	1.671	16.711	66.943
4	.845	8.450	75.393						
5	.760	7.595	82.988						
6	.553	5.533	88.521						
7	.476	4.763	93.284						
8	.350	3.496	96.780						
9	.240	2.401	99.181						
10	.082	.819	100.000						

\* Extraction Method: Principal Component Analysis

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Table 3 reveals that ten components were extracted by factor analysis using PCA with varimax rotation for scale items. The first three components (factors) in the initial solution have an Eigen value over 1, and they account for about 67% of the observed variation in the usability scale pattern among the participants. According to the Kaiser criterion having Eigen value of >1 only should be considered for interpretation.

We can draw two possible conclusions based on the output of the factor analysis with three extracted factors (see Table 3). The first conclusion is in line with research methodologists such as Neal Schmitt[38] and Naomi Kamoen[39] that the positively formulated items in this questionnaire make up the first factor and the negatively formulated items (except the 'Short learning curve'-item) the second and third factors. It is a rather common pattern that reverse-phrased items load on a different factor,[38] since people do not express the same opinion when they have to evaluate a negatively phrased item instead of a positively phrased one.[39] People tend to express their opinions more positively when a questionnaire item is phrased negatively.[39] However, it can be expected that the three factors measure the same underlying construct, since they correlate considerably in a negative direction. It is after all expected that participants who score highly on the negatively phrased items (hence, dislike the platform), do not score highly on the positively phrased ones.

When looking at the content of the items in the three factors in Table 4 and the variance patterns in Table 3, however, we can align our second possible conclusion with that of Bandor et. al[36] and that is that the common thread of items 1, 3, 5 and 9 revolves around the usability of the platform to the user. This factor accounted for 29.6% of the total variance among the VMMC patients. Items 6, 8 and 10 revolved around the level of learning the user had to undergo to use the platform efficiently and accounts for 24.8% of the variance. This also holds true for the third factor (items 2, 4 and 7) which accounts for 12.6% of the variance. The difference between the two factors is that factor 2 deals with the perceived technical complexities inherent to the platform itself (external) and factor 3 deals with the user's perception of his own ability to learn and adapt to the platform (internal).

### Internal Reliability Analysis

We ran a reliability analysis using SPSS version 24[37] on the 10-item scale with an overall Cronbach's alpha score of 0.648.

Table 3 shows 10 items and item-total statistics for the participants reflecting their total scores adding up to Cronbach's alpha of 0.648. The grand mean was  $2.51 \pm 0.82$ . The lowest mean for any item was given in response to the statement, "I thought this system was easy to use" (mean  $2.14 \pm 1.07$ ) did not differ significantly from the highest mean "I found this system unnecessarily complex" (mean  $2.99 \pm 1.81$ ).

We ran reliability analysis separately for the three factors and found the first two alpha values higher than the overall scale. The usability factor scored an alpha value of 0.799 (Grand mean= $2.31 \pm 0.91$ ), the external-learnability factor scored an alpha value of 0.738 (Grand mean= $2.73 \pm 0.43$ ) and the internal-learnability factor scored a low alpha value of 0.528 (Grand mean= $2.56 \pm 0.15$ ).

Table 3: VMMC patients' attitude towards m-Health platform

Item-total statistics; Cronbach alpha=0.648	Mean	Std. Deviation	N	Scale Mean if Item Deleted	Scale Variance if Item Deleted	Corrected Item-Total Correlation

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1-Use frequently	2.47	0.79	538	22.6487	24.806	.423
2-Unnecessary complex	2.99	1.28	538	22.1208	24.799	.185
3-Easy to use	2.14	1.07	538	22.9777	24.845	.261
4-Tech support needed	2.40	1.28	538	22.7156	22.319	.398
5-Functions well integrated	2.29	0.84	538	22.8327	26.776	.148
6-System inconsistencies	2.95	1.15	538	22.1673	22.289	.478
7-Short learning curve	2.29	1.04	538	22.8290	24.250	.337
8-Cumbersome to use	2.54	1.13	538	22.5762	25.921	.138
9-Confidence using system	2.35	1.04	538	22.7732	24.340	.329
10-Pre-knowledge needed	2.69	1.23	538	22.4294	21.854	.469

### **Focus groups**

We used content analysis on the transcripts of the five focus groups to judge how the user experienced the mHealth tool. The first author, who worked closely with the participants and were present during the interpretation, undertook the initial analysis while the other co-authors who were not part of the data-gathering phase assisted with the interpretation of the results.

We present the results of the focus group analyses based on the four topics explored in the discussions: message frequency, message comprehension, the intrusiveness of the tool, and the impact on behaviour and attitudes.

### **The frequency of the messages**

Participants generally did not have an issue with the frequency of the messages. Prior to enrolment, the study team went to great lengths to inform the study participants on the general flow and frequency of the messages over the six-week recovery period. The men knew of the increased frequency of the system at the beginning of the programme (two messages per day) with a gradual tapering of the message frequency at the end (one message every third day).

*"I found them really informative and I used them to my benefit."* (41-year old, Male)

*"I must again say that I did not have a good time and the messages kind of helped me in a way that I didn't feel so alone."* (34-year old, Male)

There were a few negative comments when some participants realised, retrospectively, the burden and reality of six weeks of messaging and the length of the commitment the programme required from them:

*"The system scared me a little in the beginning with a lot of messages, but it kind of settled afterwards."* (24-year old, Male)

*"To tell you the truth, I didn't like it. It was too much. I couldn't wait for it to be over"* (56-year old, Male)

### **The content of the messages**

Most of the participants appreciated the narrow focus and contextual nature of the messages, which moved away from general educational sound bites they have come to be familiar with in the public health sector, to more relevant advice for their plight at that moment:

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*"I liked the messages. They made sense for me, you know? It wasn't general nonsense, but it dealt with issues as they were happening to me. I guess a lot of thought went into them, right?" (44-year old, Male)*

*"I really liked the advice in the beginning but I also liked the motivation at the end." (22-year old, Male)*

### **The perceived intrusiveness of the tool**

The short 90 to 120-second audio messages were designed to have the least impact on the participants' lives and during the formative and planning phase, it was decided that one daily message around the middle of the day had the least potential of doing so. Comments generally reflected this sentiment.

*"It was fine with me" (29-year old, Male)*

The one drawback of the mid-day message delivery, was the potential clash with those who worked in a 'no-mobile phone' workplace.

*"I was in trouble at work because I wasn't allowed to take call in the shop and messages would come through at very inconvenient times" (31-year old, Male)*

*"Ag, you know, it got irritating after a while, but there was an end in sight" (45-year old, Male)*

The platform had a call-back facility, which automatically called the participant back if they did not answer the first call. This allowed them to navigate the messages better.

*"No it wasn't intrusive. I knew that if I was busy at the time the phone rang, I could just ignore it and they would call me back later" (37-year old, Male)*

One of the recruitment rules asked each participant to pick a preferred language in which they wanted the messages to be delivered in. The system would then save the participant in that language dataset and send the scheduled messages in that language. It did not have the facility to linguistically switch participants mid-intervention.

*"I made a silly mistake right in the beginning when that guy asked in what language I wanted the messages. I don't know why I said Afrikaans, but I did. And I soon hated the messages...Don't get me wrong, the messages were good and relevant, I just didn't like the voice of that Afrikaaner (White) guy. He sounded like those police guys that used to beat us up in the eighties (laughs)" (51-year old, Male)*

### **Reported impact on behaviour and attitude**

Most participants felt that the messaging system had a positive outcome on their behaviour and attitudes, as they were dealing with the recuperation and health issues in the recovery period. The relevancy and frequency of the messages acted as judicious reminders to the recovering men, forcing them to reflect and plan their behaviour.

*"I guess what I am trying to say is that no-one is going to force you to do anything... Or stop you from doing anything. I feel the messages are nice reminders of what we are supposed to do, but that's all they are, reminders. It all comes down to you" (39-year old, Male)*

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*“This is a good thing. It made me not so lonely. That I was on my own, you know?”* (19-year old, Male)

As effective as the men found the programme, some of them did not adhere to the messages.

*“(Laughs) It was okay, didn’t stop me from having sex last Saturday though...”* (29-year old, Male)

## DISCUSSION

This sub-study, stemming from the larger randomised controlled trial, was positioned to look specifically at the level of usability and user acceptance of the platform that transmitted the audio messages to the participants, and, ultimately, whether the platform could be transferable to successfully act as a vehicle to other public health behaviour modifying interventions.

The results from the two data collection techniques (SUS usability scale and focus groups) were synthesised, triangulated and analysed to provide the most comprehensive picture of the user experience of the m-Health tool.

### The level of usability of the platform

Usability of the platform was rated medium to low with a SUS usability scale mean of 62.80 (SD 13.41), which is below the industry-standard usability mean score of 68[35]. The low score underscores the fact that the intervention needs to be adjusted and improved. The rate of delivery and the level of intrusiveness of the intervention in the participants’ daily lives have been raised in the focus groups and must be taken into account for the further development of the platform. This should be tested in a large cohort study or cohort multiple randomized controlled trial as the next stage in m-Health evaluation.[40] Products or interventions with SUS scores below 70% should be considered a candidate for increased scrutiny and continued improvement.[36] [33], [35]

### The SUS instrument

Although this usability assessment instrument is regarded as an industry-standard tool, it has never been tested in this population. The below-par mean could just mean that the instrument needs to be adjusted for this environment in terms of language and cultural context. We conducted a factor analysis on the items of the scale and found, as described in the literature, that the scale has a multi-dimensional nature with three factors explaining 66.9% of the total variability.[33], [35] When we recalculated the alpha values of the items of each of the factors separately, the eigenvalues of the first two factors, Usability and External Learnability, increased significantly. This shows a strong relationship between the items in both factors.

### The Focus Groups

The participants of the programme generally received the frequency of the messages positively due to their pre-knowledge of the rate of the message delivery before the programme started. The men also found the content of the messages relevant because the timing of their delivery coincided with specific health or recuperation issues the men were grappling with. The men judged the programme’s level of intrusiveness with how well it was integrated with the running of their daily lives. A participant tended to view a message more negatively if it was ‘pushed’ to him at work that had a ‘no-cell phone’ policy. Over-all, it was a positive review, although some of the participants got tired of the messages towards the end of the programme.

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## CONCLUSION

This study demonstrates the application of systematic usability method and how researchers may take into account relevant patient characteristics during mHealth system interactions. These considerations are consistent with the predicted growth in mHealth usage rates.[41] The overall satisfaction results indicated low to medium usability. In fact, more than one-third of the participants gave the system a rather poor usability rating. This indicates a definite need for system improvements. In this sample, demographic and performance trends indicated that males living with their partners and who reported themselves with more risk performed slightly better and had higher SUS scores. These trends point to specific areas, especially for users with specific needs for additional counselling. Therefore, designers may also need to tailor interactions for the more targeted neutral users. Most of the participants were positive about the messages and felt that the messages were on point and addressed issues that were relevant to them at that particular time. This aspect of the study is congruent with other literature indicating mHealth interventions need to be better adapted to a wide variety of users to facilitate wider usage for a larger number of users.[42] We can also conclude that these tools should not be used in isolation. They need to be part of a larger more comprehensive intervention.

The present study addressed a gap in the literature by examining participants with a variety of characteristics and opinions on a set of measured outcomes. Trends such as those seen here can help developers interpret user needs in designing more usable m-Health systems. To increase the scale of m-Health use to promote wider use and wider acceptance, these kinds of user characteristics will likely need to be considered more thoughtfully in system design in the future.

## Limitations

Our qualitative study involved a small user sample from a specific clinic population, which may make it difficult to generalize findings to the general population. These users were selected from the larger database of a m-Health VMMC intervention study, using a convenience sampling technique. The sample size of 579 subjects in the SUS rating scale is appropriate for usability testing and is much greater than sample sizes recommended by Nielsen and Landauer[43], and Virzi.[44] However, these users may not be representative of all m-Health users who seek VMMC procedures. Future research in the area could explore other m-Health technologies as well as repeating this study on a greater scale with larger, randomly selected user samples to determine satisfaction outcomes. In summary, this system focused on VMMC specifically, but the findings may also have broader applications for product designs of other chronic disease applications.

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